University of Dundee

DOCTOR OF PHILOSOPHY

Episiotomy use at operative vaginal delivery

Macleod, Maureen

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Degree of Doctor of Philosophy

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Declaration

I hereby declare that I, Maureen Macleod, am the author of this thesis; that, unless otherwise stated, all references cited have been consulted by myself; that the work, of which the thesis is a record, is my own, and that it has not previously been accepted for a higher degree. All quotations have been distinguished by quotation marks and all sources of information acknowledged.

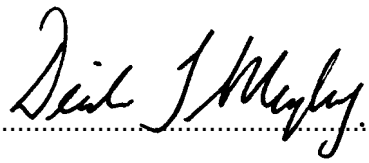
Signed……

Maureen Macleod

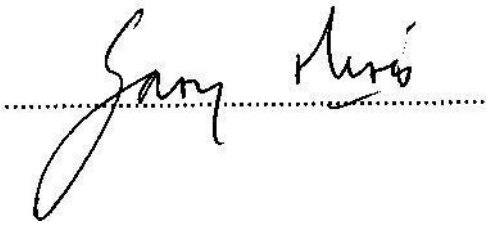
Date……

Statement

I certify that Maureen Macleod has fulfilled the conditions of the University of Dundee and that she is qualified to submit the accompanying thesis in the application for the degree of Doctor of Philosophy.

Signed 

Professor Deirdre J Murphy, Principal Supervisor

Signed 

Professor Gary J. Mires, Local Supervisor

Date 20/3/11

Abstract

Episiotomy, a component of operative vaginal delivery (OVD), aims to prevent anal sphincter tears and associated sequelae. Robust evidence suggests restrictive use should be adopted at vaginal delivery but poor quality contradictory evidence exists at OVD. This thesis concerns a series of studies conducted to address this gap in knowledge.

Formative work established *a priori* views and current practice of all obstetricians in the UK and Ireland via a national survey. The majority of clinicians preferred routine use of episiotomy at forceps delivery and restrictive use at vacuum. Respondents indicated support for the planned pilot RCT.

A feasibility study established the possibility of conducting a pilot RCT with its known complexities. Data collection tools were developed and found to be fit for purpose and acceptable to women. Shortcomings in the study design informed the proposed pilot RCT.

Contemporaneous to the pilot RCT, we conducted a prospective cohort study (n=1360) of morbidity in relation to episiotomy use at OVD to contextualise its findings. Episiotomy was not found to be protective of anal sphincter tears, shoulder dystocia or neonatal trauma but was associated with an increased risk of postpartum haemorrhage [adjusted OR 1.72 (95%CI 1.21 – 2.45)], perineal infection [adjusted OR 4.04 (95%CI 1.44 – 11.37)] and analgesic use [adjusted OR 3.35 (95%CI 2.49 – 4.51)].

The two centred pilot RCT, while not powered to provide definitive evidence, suggested a restrictive approach to episiotomy use does not appear to reduce or greatly increase anal sphincter tears [8.1% vs 10.9%, adjusted OR 0.77, (95% CI 0.28 – 2.10)]. There may however be a difference in effect size and direction between vacuum and forceps use. Routine use was associated with an increase in PPH [36% vs 27%; adjusted OR 1.88, (95% CI 0.99 - 3.57)]. A longitudinal follow up of participants to one year postpartum

suggested routine use of episiotomy may decrease rates of urinary morbidity, particularly stress incontinence; dyspareunia; and perineal pain compared to restrictive use.

This pilot RCT supports current practice regarding approach to episiotomy use at OVD meantime, pending the results of a definitive study.

Abbreviations

AI	Anal incontinence
BFLUTS	Bristol Female Lower Urinary Tract Symptoms
BMI	Body mass index
BPI	Brachial plexus injury
CI	Confidence interval
CS	Caesarean section
CTG	Cardiotocograph
EAS	External anal sphincter
EPDS	Edinburgh postnatal depression score
FDA	US Food and Drug Administration
FP	Family practitioner
GP	General Practitioner
IAS	Internal anal sphincter
IPPV	Intermittent positive pressure ventilation
IUGR	Intra uterine growth restriction
MRC	Medical research council
MRI	Magnetic resonance imaging
NICU	Neonatal intensive care unit
OA	Occipito anterior
OP	Occipito posterior
OR	Odds ratios
OT	Occipito transverse
OVD	Operative vaginal delivery

PPH	Primary postpartum haemorrhage
PPI	Present pain intensity
PRI	Pain rating index
PTSD	Post traumatic stress disorder
QOL	Quality of life
RCOG	Royal College of Obstetricians and Gynaecologists, UK
RCT	Randomised controlled trials
RR	Relative risk
SGA	Small for gestational age
SHO	Senior house officer
SpR	Specialist registrar
SPSS	Statistical Package for Social Scientists
SSHO	Senior house officer
SVD	Spontaneous vaginal delivery
UI	Urinary incontinence
VAS	Visual analogue scale
WHO	World Health Organisation

List of publications arising from this thesis

Operative vaginal delivery and the use of episiotomy – A survey of practice in the United Kingdom. (2007) **Macleod M,** Murphy DJ. *Eur J Obstet. Gynecol*; 136:178-183

A prospective cohort study of maternal and neonatal morbidity in relation to the use of episiotomy at operative vaginal delivery. (2008) **Macleod, M.** Strachan, B. Bahl, R. Howarth, L. Goyder, K. Van de Venne, M. Murphy, DJ. *BJOG* ;115:1688–1694

A randomised controlled trial of routine versus restrictive use of episiotomy at operative vaginal delivery: a multicentre pilot study. (2008) Murphy, DJ. **Macleod, M.** Bahl, R. Goyder, K. Howarth, L. Strachan, B. *BJOG* ;115:1695–1703

A Randomized Controlled Trial of Routine versus Restrictive Use of Episiotomy at Operative Vaginal Delivery: A Multicentre Pilot Study. (2009) Murphy, D.J. **Macleod, M**. Bahl, R. Goyder, K. Howarth, L. Strachan, B. *Obstetrical and Gynecological Survey*; 64:4:220 (abstracted and critically reviewed)

Presentations

Macleod, M. A prospective cohort study of maternal and neonatal morbidity in relation to episiotomy use in operative vaginal delivery. (2007). *In: Proceedings of the Inaugural Researching Midwifery Conference*, University of Dundee (unpublished).

Chapter 1 - Introduction And Review Of The Literature

1.1 Introduction

This thesis is concerned with a group of studies that were designed to explore the role of episiotomy at operative vaginal delivery (OVD) and its relationship to anal sphincter tearing by comparing two approaches common within obstetric practice; routine versus restrictive use. This chapter will introduce and review the literature in respect of the obstetric procedures relevant to this work, namely OVD and episiotomy, and describe the associated maternal and neonatal morbidities.

1.2 Search Strategies

A search of the literature was performed using the electronic bibliographic databases of Ovid Medline from 1966 to 2011 and the Cochrane Library database using terms independently and in combination: obstetrics, pregnancy, instrumental or assisted delivery, operative vaginal delivery, labour complications, trends, episiotomy, forceps delivery, vacuum extraction, morbidity, perineal trauma, newborn, birth trauma. Where possible systematic reviews were identified using the Cochrane Pregnancy and Childbirth Database of Systematic Reviews and guidelines and protocols were searched for using the website of the Royal College of Obstetricians and Gynaecologists (RCOG). Some statistics were sourced from the BirthChoiceUK website.

1.3 Background

Following the medicalisation and increasing use of interventions in obstetric care over the latter half of the 20th century, a change of emphasis for the care of "low risk" women towards normalisation of pregnancy and the birth experience has come to be accepted as

best practice in recent years [A Framework for Maternity Services in Scotland, (Scottish Executive 2001)].

Despite this, one in four women experiencing childbirth for the first time in the UK is advised to have their delivery assisted by the use of obstetric forceps or vacuum extractor [Births in Scotland reports, vol. 4, (NHS Scotland 2003)]. A great deal of attention has been paid to technical aspects of such deliveries (Johanson and Menon 1999, Majoko and Gardener 2008) but little research has investigated the role of episiotomy within OVD with regard to perineal tearing and subsequent morbidities in both the mother and her infant. Episiotomy is a modifiable behaviour with regard to OVD (Hudelist et al. 2008) and therefore it is both timely and important that its role at OVD be investigated.

1.4 Operative vaginal delivery

Operative vaginal delivery can be defined as vaginal delivery that is expedited by the assistance of obstetric forceps (Figure 1.1) or vacuum extractor (Figure 1.2). It is employed with the aim of accelerating delivery in the case of fetal or maternal distress particularly if the second stage of labour is prolonged.

Figure 1.1 Obstetric forceps

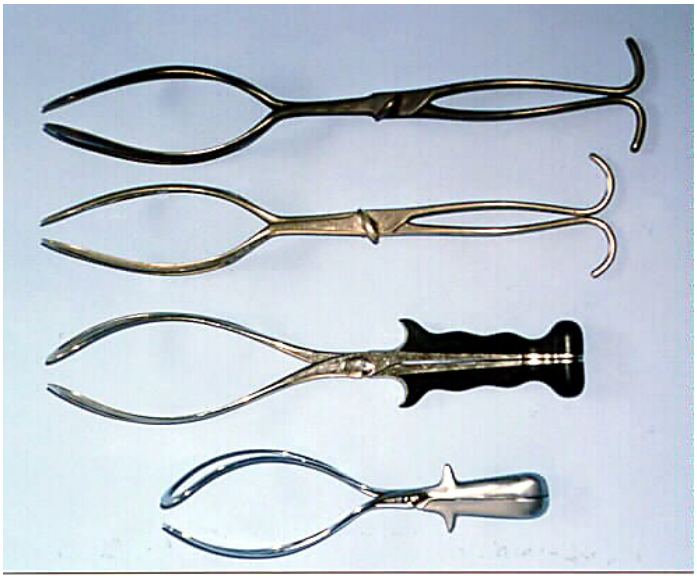


Figure 1.2 Ventouse or vacuum extractor

Indications for OVD include a perceived fetal compromise or a failure to progress in the second stage of labour, commonly secondary to malposition of the fetal head or poor maternal effort. Cheng et al. (2004) conducted a retrospective cohort study of 15,759 primigravid women and concluded that maternal morbidity increased significantly when

the second stage of labour exceeded three hours. Other commentators have recommended restriction of the active phase of the second stage of labour to no longer than one hour in primiparae and shorter than that in multiparae (Sizer et al. 2000; Murphy 2001). Current guidance from the RCOG (Greentop guideline No 26, 2011) suggests inadequate progress as an indication for OVD – in nulliparous women a second stage (both active and passive phases) lasting three hours with regional anaesthesia or two hours without; multiparous women two hours and one hour respectively. Timely intervention in the second stage of labour is therefore a balance of the risks of continued pushing against the risk of morbidity associated with OVD (Murphy 2001).

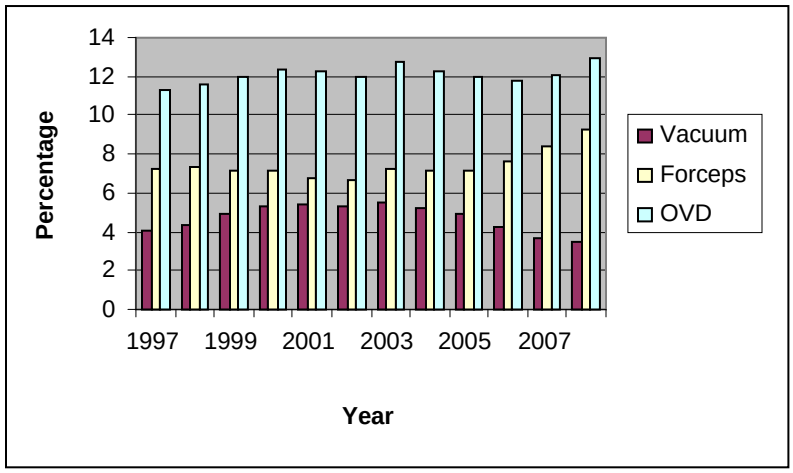
1.5 Incidence of operative vaginal delivery and instrument choice

Evidence suggests that there is wide variation in OVD rates with no standardised approach to the use of instrument at OVD.

The Scottish Perinatal and Morbidity Review Advisory Group of NHS Scotland produced the 4th Births in Scotland volume, Operative Vaginal Delivery in Scotland: a 20 year overview (2003). For the period 1981 to 2000, they established 10.2% of all singleton, cephalic births were forceps deliveries and 2.0%, vacuum. Hospital level OVD rates varied for the period 1996-2000 from 10.1% to 33.8%. Whereas, "the overall operative vaginal delivery rate over time had remained virtually constant around 12%.....the proportional use of vacuum rather than forceps had increased steadily year on year." Statistics show the forceps rate has fallen from 13% in 1981 to 7.0% in 2000 though the vacuum rate increased from 0.4% in 1981 to almost 6.0% in 2000. Data from BirthChoiceUK suggest that, in Scotland especially, this increase in the use of vacuum may have peaked around

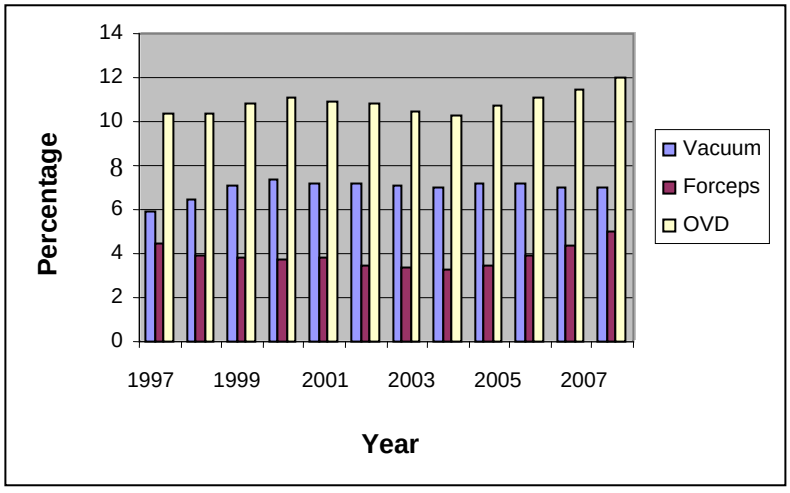
the turn of this century and even begun to decline in recent years with a return to favouring assistance by forceps (Figures 1.3, 1.4).

Figure 1.3 Operative vaginal delivery rates in Scotland, by instrument 1997 to 2008



Source: BirthChoiceUK.com

Figure 1.4 Operative vaginal delivery rates in England, by instrument 1997 to 2008



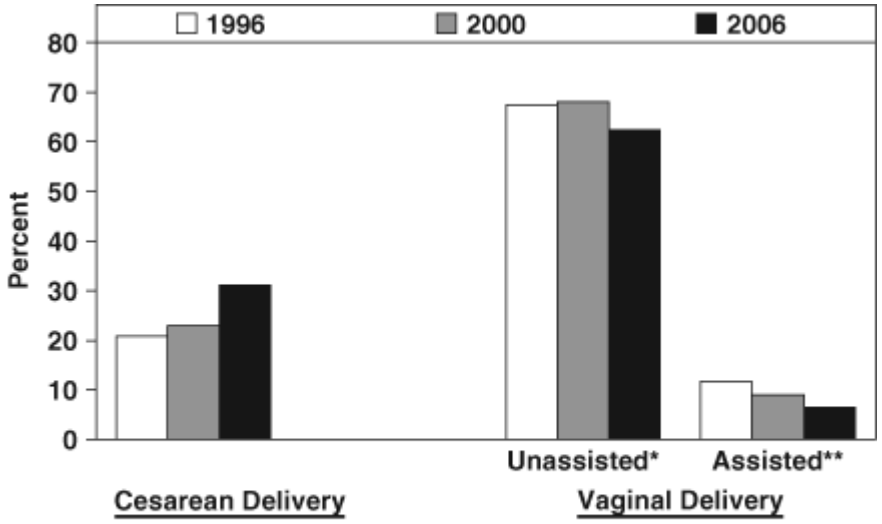
Source: BirthChoiceUK.com

Alran et al. (2002) conducted a survey of obstetric practices in nine tertiary referral hospitals in Europe between November 1999 and October 2000. They identified considerable regional variation without any major difference in maternal and perinatal mortality. The OVD rate varied from three per cent in Perugia to 40% in Barcelona and the caesarean section (CS) rate from 12% in Paris to 32% in Athens.

In the US, Kabiru et al. (2001) described a retrospective cohort study (1980-1996) of women with a singleton, term delivery who underwent OVD at a hospital in Atlanta, Georgia. Their results showed there was a decline in forceps assisted deliveries during the 1980s and an increase again during the 90s while the vacuum assisted rate was very low during the 1980s and increased during the 1990s. They concluded there was an overall upward trend in the rates of OVD at this inner city hospital.

An analysis of Birthstats over a ten year period from 1996 – 2006 (Menacker and Martin 2009) reported a 50% rise in the CS rate in the US from 20.7% to 31.1%. Over the same time period the rate of OVD dropped from 11.8% to 6.6%. The pace of these changes reportedly accelerated between 2000 and 2006 (Figure 1.5).

Figure 1.5 Rates of delivery by mode in the US 1996 to 2006



*Vaginal delivery without the use of vacuum extraction or forceps.
**Vaginal delivery with the use of vacuum extraction or forceps.
Source: NCHS/CDC/National Vital Statistics System, 1996, 2000 and 2006

Martin et al. (2005) observed a forceps assisted delivery rate in the US of only 5.9% in 2003. This represented a decline of 60% since 1994. Concomitant with this decline, there has been a rise in the vacuum extraction rate. Demissie et al. (2004) found that in their cohort, between 1995 and 1998, 67% of OVDs were by vacuum extraction and 33% by forceps. Similar findings were reported by Frankman et al. (2009) – a decline in the rate of OVD from 8.7 per 1000 women in 1974 to 4.6 per 1000 women in 2004.

Menacker and Martin (2009) suggested this picture may reflect changes in obstetric training and practice patterns but may also be in part a response to the ongoing debate in the medical press regarding the immediate and longer term risks and benefits of vaginal versus caesarean birth for women and their infants. This debate may be even more critical in the litigious American health care system.

This shift towards the use of vacuum was supported by Johanson and Menon (1999) in their Cochrane Library systematic review of ten randomised controlled trials (RCTs) comparing delivery by forceps and vacuum extraction. They reported use of the latter was

associated with significantly less maternal trauma (Odds Ratio (OR) 0.41, 95% Confidence Interval (CI) 0.33 – 0.50) and with less general and regional anaesthesia however this group was associated with an increase in neonatal cephalhaematoma and greater maternal concern about the baby. Fewer CSs were carried out in the vacuum group which the authors accounted for by the fact that after failed vacuum, delivery can usually be accomplished by forceps delivery whereas failed forceps leads to delivery by CS. They also suggested that vacuum may be more effective in circumstances in which forceps would be more likely to fail e.g. malposition of the fetal head. They concluded that current evidence suggests that, where OVD is required, vacuum should be the instrument of first choice.

In contrast Weerasekera and Premaratne (2002) who conducted a randomised controlled trial of 442 women concluded from that forceps used under strictly defined criteria (< three pulls , delivery of the fetal head in the occipito-anterior position) compared to vacuum extraction for delivery in the second stage of labour led to no significant differences in the incidence of third degree perineal tears, post partum haemorrhage or ruptured uterus. Cervical tears were slightly more common in the forceps group. Although the vacuum group showed a higher incidence of cephalhaematoma there was no significant difference in the number of babies needing resuscitation at birth, admission to neonatal intensive care or neonatal death rates. The failure rate was significantly higher in the vacuum group. They concluded that, when performed under defined criteria, forceps deliveries are as safe as vacuum deliveries to the mother with a lesser failure rate and a lower incidence of cephalhaematoma.

Demissie et al., (2004) in a large population based study compared the risk at vacuum delivery with that at forceps delivery of neonatal and infant mortalities and morbidities up to one year of age. They found no differences in mortality rates between births assisted by vacuum and forceps. Vacuum was found to be associated with a lower risk of birth

injuries, neonatal seizures and need for assisted ventilation however was more likely to be complicated by postpartum haemorrhage (PPH) and shoulder dystocia. They concluded then that, although vacuum delivery does have risks, it is a safe alternative to forceps delivery.

The current RCOG Green top guideline on OVD (No 26) states that "safe operative delivery requires careful assessment of the clinical situation, clear communication with the mother and healthcare personnel and expertise in the chosen procedure." And so it is left to the delivering clinician to best assess the instrument of choice in each individual circumstance taking into account their level of skill and the clinical findings.

McQuivey (2004) raised concerns that the training afforded to the use of forceps in the past was not being given to vacuum due to its perceived ease of use. They suggested that this lack of preparedness for its use has led to an increasing numbers of complications.

There is some evidence that the grade and gender of the operator influences the choice of instrument at OVD. Allen and Hanson (2005) in a retrospective cohort study performed in a large community hospital in Boston, US reported that obstetricians were three times more likely to use forceps than Family Practitioners (FPs) whereas their vacuum extraction rate was one tenth of that of FPs. Bonar et al. (2000) examined the effect of operator gender on the forceps delivery rate in more than 350,000 deliveries across the US, from 1994 to 1998, by 800 plus obstetric physician residents. They found the percentage of overall OVD was significantly higher for male operators ($p<0.001$) as was the percentage of forceps assisted deliveries ($p<0.001$) during their residency period whereas the rate of vacuum assisted deliveries did not vary according to operator gender.

It would appear the debate about instrument preference will continue to be played out in the medical press, however, in conclusion, it would appear that in the UK the overall rate of OVD is fairly constant but with variation at a hospital and individual level in the

frequency of OVD and the choice of instrument used. This variation has also been observed in other parts of Europe and the US.

1.6 Anatomy of the anal sphincter complex and pelvic floor

The anal sphincter complex (Figure 1.6) comprises three elements – the external anal sphincter (EAS), internal anal sphincter (IAS) and the epithelial lining of the anal mucosa. The EAS is a tear drop shaped circle of voluntary muscle which surrounds the lower two thirds of the anal canal. The deep part of the EAS along with the adjacent puborectalis muscle maintains the anorectal angle which plays a vital role in the continence of faeces by sustaining voluntary contraction thereby maintaining closure of the lumen of the anal canal to prevent uncontrolled passage of faeces or flatus. The IAS is a thickened continuation of the smooth muscle of the rectum which extends downwards to enclose the upper two thirds of the anal canal. The subcutaneous portion of the external sphincter lies below the lower margin of the IAS. Between the internal and external sphincters lies a layer of longitudinal muscle – its action is completely involuntary and its main role is to maintain closure of the anal opening preventing involuntary passage of faeces or flatus.

Figure 1.6 Anatomy of the anal sphincter complex

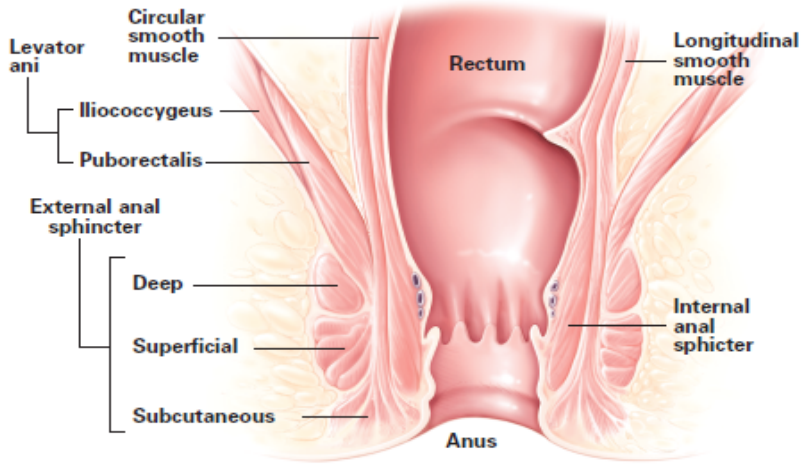
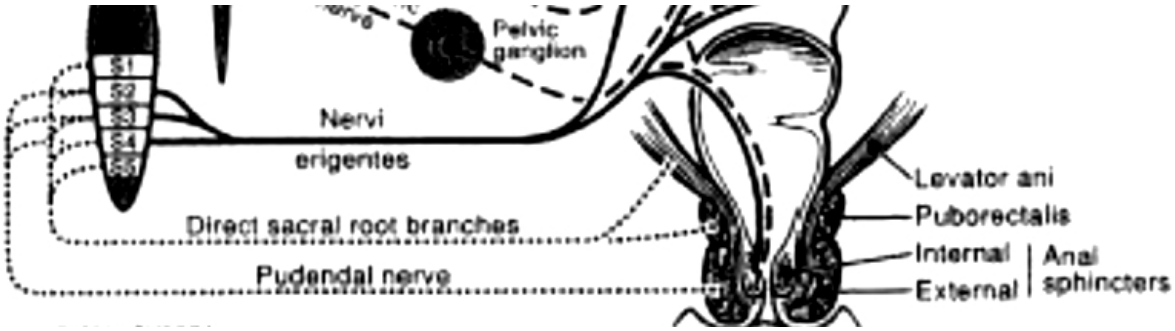


Illustration by Rich LaRocco from Power et al., 2006

An intact and innervated anal sphincter complex is required to maintain faecal continence. The anal sphincter is innervated by the pudendal nerve and the levator ani muscle is innervated both by the pudendal nerve and by motor branches of the pelvic plexus (Figure 1.7).

Figure 1.7 Innervation of the anal sphincter complex



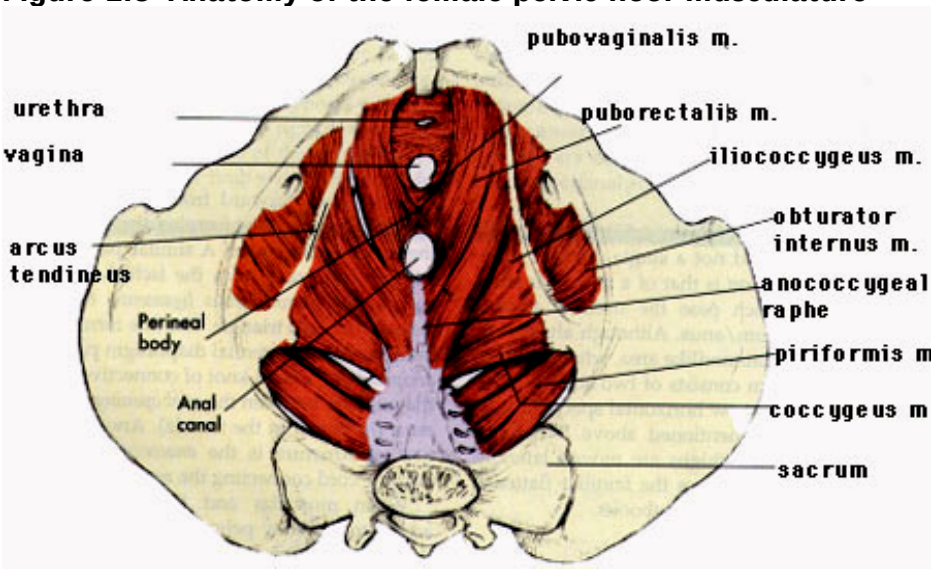
Source (Snooks and Swash 1986)

Damage to the anal sphincter complex can be mechanical and/or neurologic. Neuropathy, due to stretching of the pudendal nerves or compression of the pelvic sacral nerves, may rarely occur in isolation but is more commonly associated with mechanical damage. Mechanical injury occurs in the case of a clinically obvious or an occult third or fourth degree tear. Neuropathy may be the result of forceps delivery, persistent compression from the fetal head in the case of a prolonged second stage of labour or traction injury associated with macrosomia or prolonged pushing. Damaged nerves may undergo a degree of demyelination but will in most cases recover in time. A mechanical aetiology to damage to the anal sphincter complex can lead to early faecal/flatal incontinence whereas a neuropathic aetiology may lead to a more delayed onset.

The musculature of the pelvic floor (Figure 1.8) consists of a sling like group of muscles known as the levator ani. The levator ani comprises the pubococcygeus, puborectalis,

iliococcygeus and ischiococcygeus muscles. They support the pelvic organs and counteract any increases in abdominal pressure e.g. when laughing or sneezing and therefore help to maintain urinary continence.

Figure 1.8 Anatomy of the female pelvic floor musculature



source http://lucy.stanford.edu

1.7 Anal sphincter tears

The primary interest of this thesis is the relationship between the approach to the use of episiotomy at OVD and its subsequent impact on the rate of tears affecting the anal sphincter complex.

Accurate classification of perineal tears is vital for their correct identification and subsequent management. Fernando et al. (2002) carried out a literature review and survey of practitioners (obstetricians and coloproctologists) which revealed a lack of consistency in classification. For example, 33% of consultant obstetricians and 22% of trainees considered a complete or partial external sphincter tear to be 'second degree' as did 22% of authors of obstetric texts in the RCOG library. It was also found there was

wide regional variation in this misclassification with some regions being ten times more likely to misclassify than others.

Standardisation of the definition of perineal tears is important. The RCOG Green top guideline on Management of third and fourth degree perineal tears following vaginal delivery (2007) and guidelines by other international governing bodies have adopted Sultan's (Sultan 1999) classification of perineal tears (Figure 1.9). This classification will also be used for the purpose of this thesis.

Figure 1.9 Sultan's classification of perineal tears

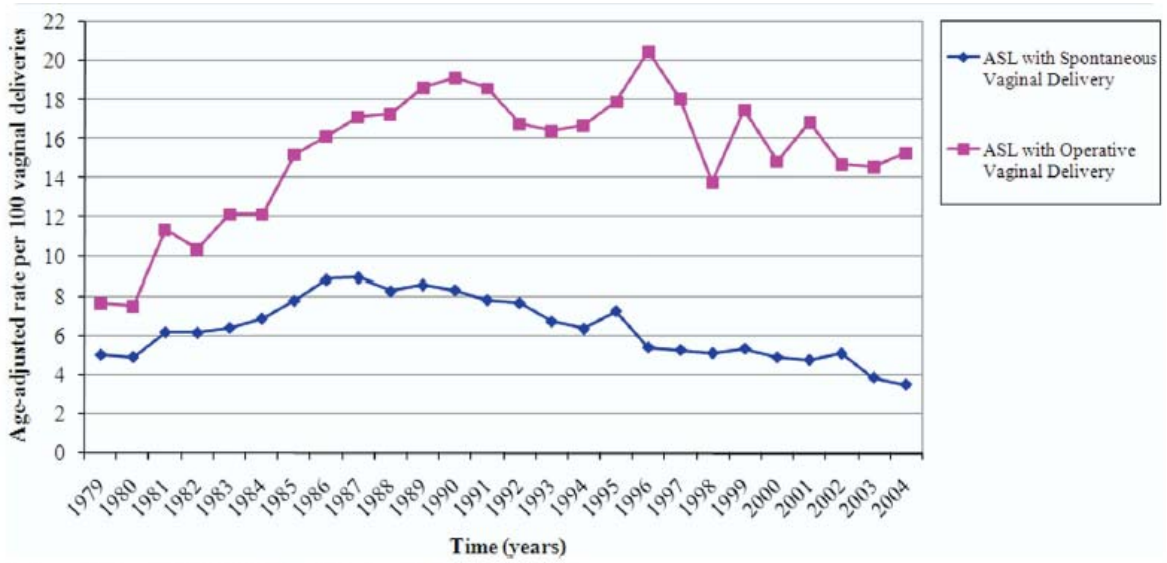
- First degree: Injury to perineal skin only
- Second degree: Injury to the perineum involving the perineal muscles but not involving the anal sphincter
- Third degree 3a: Injury to the perineum involving the perineal muscles and the anal sphincter with less than 50% of the EAS thickness torn
- Third degree 3b: Injury to the perineum involving the perineal muscles and the anal sphincter with more than 50% of the EAS thickness torn
- Third degree 3c: Injury to the perineum involving the perineal muscles and the anal sphincter with both the EAS and IAS torn
- Fourth degree: Injury to the perineum involving the perineal muscles and the anal sphincter with tearing of the anal sphincter complex including the anal mucosa

1.8 Incidence of and factors associated with anal sphincter tears

Many authors have studied the incidence of and risk factors contributing to severe perineal trauma.

Frankman et al. (2009) studied the American population to establish the age adjusted rates of differing modes of delivery and their associated rates of episiotomy use and incidence of anal sphincter tears using census data for 1990. The rate of anal sphincter tears at OVD has consistently been higher than that at SVD. The rate increased from 7.7% in 1979 to 15.3% in 2004 compared to a relatively steady rate at SVD (5% in 1979 to 3.5% in 2004) (Figure 1.10).

Figure 1.10 Age adjusted rates of anal sphincter lacerations (ASL) per 100 vaginal deliveries from 1979 - 2004 in the US



Frankman. Episiotomy in the United States: has anything changed? Am J Obstet Gynecol 2009.

Power et al. (2006) carried out a literature review of obstetric anal sphincter tearing. The reported incidence of anal sphincter tears has varied from 0.5% to 8.9% of vaginal deliveries. A number of risk factors were associated with anal sphincter tears – some

modifiable and some not – with odds ratio (OR) ranging from 1.4 for spontaneous delivery with mediolateral episiotomy to 25 for forceps delivery with midline episiotomy (Table 1.1).

Table 1.1 Major risk factors for obstetric anal sphincter injury

Risk factor	OR
Nulliparity (primiparity)	3–4
Short perineal body	8
Instrumental delivery, overall	3
Forceps-assisted delivery	3–7
Vacuum-assisted delivery	3
Forceps vs vacuum	2.88
Forceps with midline episiotomy	25
Prolonged second stage of labour (>1 hour)	1.5–4
Epidural analgesia	1.5–3
Birth weight over 4 kg	2
Persistent occipito-posterior position	2–3
Episiotomy, mediolateral	1.4
Episiotomy, midline	3–5
Previous anal sphincter tear	4

Source: Power et al., 2006

Byrd et al. (2005) also reviewed the literature (1994 - 2004) with the aim of identifying the causes of anal sphincter tearing during vaginal delivery. They identified 84 studies which reported a similar range of factors as Power et al. (2006).

There would appear to be substantial evidence that OVD and episiotomy at both spontaneous and OVD are independent risk factors for anal sphincter tears.

Interesting work has been carried out by Sultan and colleagues using anal endosonography to identify defects in the IAS and EAS. They found that all women who had bowel symptoms had an anal sphincter defect but not all women with an identified defect had bowel symptoms. This has led to some uncertainty as to the clinical significance of developing an anal sphincter defect. Sultan et al. (1993b) carried out a prospective study using anal endosonography to identify anal sphincter defects in unselected, consecutive women during the final six weeks of pregnancy (n=202) with follow up at six weeks (n=150) and six months postpartum (n=32) if problems were evident at the six week follow-up visit. No primiparae had an anal sphincter defect on antenatal anal endosonography compared to 19(40%) of multiparae. Following vaginal delivery, 3% of primiparae (2/79) and no multiparae (0/48) sustained an injury to the anal sphincter that was clinically obvious; however, on anal endosonography sphincter damage was identified in 35% (28/79) and 44% (21/48) of cases respectively. The rate of damage among primiparae at six weeks was comparable with the pre delivery rates among multiparae with only a 4% increase in the postpartum rate for multiparae. This would indicate that the risk of anal sphincter damage is greatest in a first delivery. No change was found at six month follow up in anal sphincter defects identified at six week follow up. Sphincter defects were reported in 8/10(80%) of primiparae following forceps delivery whereas none of the five primiparae delivered by vacuum sustained an injury. This finding was supported by further data presented by Sultan et al. (1993a) which compared the

perineal outcomes of 43 primiparae at OVD with 47 at spontaneous delivery. Forceps assisted delivery was significantly associated with anal sphincter defects (81% vs 36%, p=0.003) however no such association was found at vacuum delivery (21% vs 36%, p>0.05).

A further finding in the Sultan et al. (1993b) study was a significant association between episiotomy use at vaginal delivery and anal sphincter defects. Both IAS and EAS defects identified by anal endosonography was significantly associated with episiotomy use (p= 0.04 and p=0.02 respectively). In all cases external sphincter damage was in the presence of a tear or episiotomy suggesting the damage was a continuation of the perineal disruption. No association was found between birth weight, head circumference, length of labour or spontaneous tears and the presence of anal sphincter defects.

Hudelist et al. (2005) identified only high birth weight (over 4000g) (OR 1.68 95% CI 1.18 to 2.41) and forceps delivery combined with mediolateral episiotomy (OR 5.62, 95% CI 2.16 to 14.62) as independent risk factors for anal sphincter tears. Consistent with this report was a retrospective case controlled study by Christianson et al. (2003) which identified forceps as being associated with a ten-fold increased risk of anal sphincter injury compared to spontaneous deliveries (adjusted OR 11.9; 95% CI 4.7 – 30.4). Forceps were used in 51.6% of deliveries that resulted in tears compared to 8.6% of deliveries without significant tears (p<0.05). Nulliparous women were more at risk at spontaneous delivery for anal sphincter tears than multiparous women (adjusted OR 10.0; 95% CI 3.0 – 33.3) but correcting for parity as a confounder did not reduce the association between forceps assisted deliveries and anal sphincter injuries. Other risk factors identified included increasing fetal weight and performance of a midline episiotomy (adjusted OR 2.5; 95% CI 1.0 – 6.0)

Handa et al. (2001) in a population based retrospective study of over two million vaginal deliveries in California from 1992 to 1997 reported OVD increased the risk of anal sphincter laceration, with vacuum delivery (OR 2.30, 95% CI 2.21 – 2.40) presenting a greater risk than forceps delivery (OR 1.45, 95% CI 1.37 – 1.52).

Forceps assisted vaginal deliveries have then been associated with a greater risk of anal sphincter injury but Benavides et al. (2005) demonstrated that within this group anal sphincter injury occurred significantly more often in women delivered by OVD with an associated persistent occipito posterior (OP) position of the fetal head at delivery as compared with an occipito anterior (OA) position of the fetal head (51.5% vs 32.9%; adjusted OR 3.1, 95%CI 1.6- 6.2).

Episiotomy use has been repeatedly shown to have a strong association with anal sphincter trauma. Carroli and Belizan (1999) provided clear evidence that at vaginal delivery episiotomy is associated with a greater risk of anal sphincter injury. Eason et al. (2002) carried out a systematic review of techniques proposed to prevent perineal trauma during childbirth and concluded there was good evidence that avoiding episiotomy decreased perineal trauma. Retrospective studies in support of these reviews include Angioli et al. (2000) who analysed risk factors associated with severe laceration in a cohort of 50,210 women at a single large teaching hospital in Miami from 1989 - 1995. Episiotomy, episiotomy type, high birth weight, OVD and older maternal age were identified as independent risk factors for anal sphincter tears. Also Buchhave et al. (1999) conducted a retrospective case controlled study of 292 women with rupture of the anal sphincter across four hospitals in Sweden between 1988 and 1990. They found, after multivariate analysis, that only three variables were significantly associated with anal sphincter tears – birth weight $\geq$ 4000g (OR 2.6, 95%CI 1.7 – 3.9), primiparity (OR 2.2, 95%CI 1.5 – 3.3) and episiotomy use (OR 1.7, 95%CI 1.1 – 2.6).

In contrast to this, some retrospective studies have found episiotomy to have a protective role in the development of anal sphincter tearing. Poen et al. (1997) studied a cohort of 120 women whose delivery was complicated by a third degree tear during a five year period in the Netherlands. Each case was matched to six controls. They found on univariate analysis of nulliparous women that mediolateral episiotomy was associated with fewer anal sphincter tears (OR 0.46, 95%CI 0.27 – 0.77). No such protection was found in multiparous women with more risk of anal sphincter tearing being found (OR 2.12, 95%CI 1.05 – 4.28). These findings were supported in a retrospective study by Dahl and Kjolhede (2006). Their retrospective cohort study investigated the association between older age in primiparous women and anal sphincter tearing. Each of 327 cases aged 35-45 years were matched to two controls ten years younger but at the same gestational age and delivering in the same year. OVD, both forceps (OR 10.21, 95%CI 2.23 – 46.81) and vacuum (OR 5.36, 95%CI 2.78 – 10.32) were found to be independent risk factors for anal sphincter tearing along with head circumference (OR 1.38, 95%CI 1.06 – 1.80) but episiotomy use was found to be protective of anal sphincter tearing (OR 0.29, 95%CI 0.14 – 0.63).

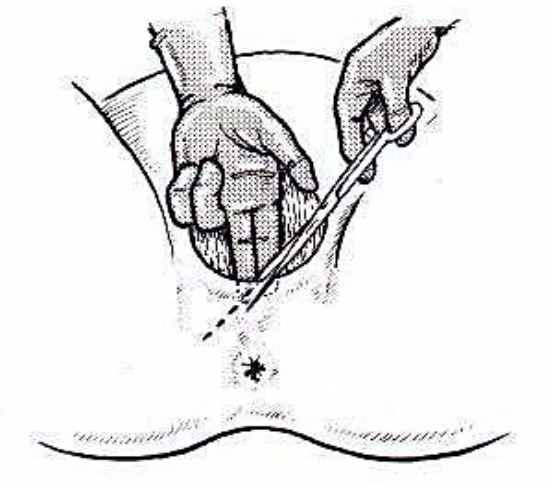
The balance of evidence from higher quality RCTs and prospective trials therefore supports the fact that OVD and episiotomy are risk factors for anal sphincter injury.

Having established this it would be prudent to further investigate whether this association is causal and if it is modifiable.

1.9 Episiotomy

Episiotomy is an incision in the perineum performed during the last moments of the second stage of labour and has traditionally been an element of vaginal delivery. Originating from the fourchette at the perineal midline, the episiotomy is cut at an angle ranging from 0° if midline episiotomy to 90° in lateral episiotomy (Figure 1.11).

Figure 1.11 Right mediolateral episiotomy



The obstetric use of episiotomy was first recorded in the literature by Sir Fielding Ould [A Treatise of Midwifery,(Ould 1742)]. Over the next 200 years or so episiotomy, in one form or another, was used as an intervention of last resort but it wasn't until the 20th century that the routine use of episiotomy grew in popularity, firstly during the 1920-30s in the United States (DeLee 1920; Pomeroy 1918) and later in the UK.

Until the 1950s in the UK there was a dichotomous view of childbirth with the midwife as practitioner for normal births at home and obstetricians caring for the abnormal in the hospital setting. Over the next two decades this model of care for women in childbirth changed so that by 1968 80% of births took place in hospital. Following the Peel Report (Peel 1970), which recommended that all births should be hospitalised, the home birth rate significantly reduced further to just three per cent. The swing from home based to hospital based care meant that women were being cared for increasingly by obstetricians with surgical skills and midwives lost some degree of their autonomous practice and role as main decision maker.

With hospital births becoming more the norm in the UK, the routine use of episiotomy crept in to practice. Butler and Bonham (1963), in their first report on the 1958 British Perinatal Mortality Survey, reported that episiotomy was performed in only two per cent of homebirths. By the late 1960s, the UK episiotomy rate of all births had risen to 25% and over the next decade increased to over 50%, and as high as 90% for primiparae (Macfarlane and Mugford 1984).

The rationale – imported from the US, in an era before rigorous evaluation of an intervention informed clinical practice – suggested episiotomy was performed with the aim of preventing extensive perineal tearing extending to include involvement of the anal sphincter. It was thus thought to be protective of maternal morbidities such as sexual dysfunction, urinary and faecal incontinence following a difficult vaginal delivery (DeLee 1920; Pomeroy 1918). There was also a body of opinion that stated episiotomy was preferable to spontaneous tearing because it was "easier to repair" (Larsson et al. 1991). Episiotomy was also employed to expedite delivery which, if delayed, may have detrimental implications for the neonate such as birth asphyxia, cranial trauma and cerebral haemorrhage. Lastly, episiotomy was thought to have a useful role to play in preventing mechanically induced morbidities associated with shoulder dystocia, for example brachial plexus injury (BPI) in the neonate.

Modern day practice in the UK, Western Europe and Australia employs a mediolateral approach to episiotomy whilst North America favours a midline approach. The rationale behind a mediolateral approach to episiotomy, in which the cut is directed laterally and downwards at an angle of 40°-60°, is that any subsequent tearing is directed away from the anal sphincter to avoid its injury. A recent study (Delancy 2008) has suggested that the optimal angle of the episiotomy, to avoid anal sphincter damage, requires it to be greater than 40° as the angle at which the incision is made varies from the angle of

episiotomy at repair. For example, an episiotomy cut at an angle of 45° when the perineum is distended by the fetal head may in fact be an incision angle of 25-30° postpartum and may be in the area of the sphincter muscles and so he advocates an angle closer to 60°. Further evidence from Kalis et al. (2008a) supports this viewpoint. This group concluded from their prospective cohort study of 50 consecutive women undergoing their first vaginal delivery that 40° may be too acute to avoid anal sphincter damage. Eogan et al. (2006) reported a 50% relative reduction in risk of sustaining a third degree tear for every 6° away from the perineal midline an episiotomy was cut. Rather than using the angle of incision in defining mediolateral episiotomy Karbanova et al. (2009) used the ischial tuberosity as a reference point and measured the angle of incision of 50 consecutive women delivered by a single accoucheur using the direction routinely used in their hospital as "towards the ischial tuberosity". The median incision angle was found to be 63° which is within the recommended range of Kalis and DeLancey. Although not commonly used in obstetric guidelines in the UK this may yet prove to be a more easily identifiable and reliable reference point for a safe angle of incision.

A survey of 122 European hospitals by Kalis et al. (2008b) reported widely differing definitions of mediolateral episiotomy in usage with some respondents mistaking other types of episiotomy as mediolateral with 14 "novel" definitions cited. Tincello et al. (2003) in their study asked practitioners to draw the angle of cut they would employ in mediolateral episiotomy on a two-dimensional drawing of the perineum at crowning of the fetal head. In 33% of cases operators originated their episiotomy lateral to the perineal midline and 23% of midwives and two per cent of doctors indicated an angle of 30° or less. Andrews et al. (2005) measured the angle of episiotomy from the midline after repair and reported 13% of physicians and none of 40 participating midwives performed an episiotomy within the reference range of 40-60°. These findings indicate some difficulty

with the definition of episiotomy types among practitioners which may have significant implications for anal sphincter protection, a principal aim of performing an episiotomy.

1.10 Risk factors for episiotomy

Weber and Meyn (2002) in their review of US episiotomy use found women undergoing episiotomy had different characteristics from women who did not receive episiotomy. They were slightly younger (mean 25.7 vs 26.2 years, $p<0.001$), less likely to be black [black 39% vs white 60%, adjusted OR 0.46(95%CI 0.45 – 0.48)] and more likely to have private insurance than government insurance (62% vs 43%, adjusted OR 0.54(95%CI 0.53 – 0.56)].

Robinson et al. (2000) also identified labour factors such as prolonged second stage of labour (OR 1.8, 95%CI 1.2 – 2.7), fetal macrosomia (OR 1.6, 95%CI 1.1 – 2.5) and epidural analgesia (OR 1.4, 95%CI 1.1 – 1.8) as associated with increased risk of episiotomy use at spontaneous vaginal delivery (SVD). OVD however remains the most significant risk factor associated with the use of episiotomy. Allen and Hanson (2005) reported an episiotomy rate of 84%, adjusted OR 5.08(95%CI 3.75 – 6.88) and 62% adjusted OR 2.85(95%CI 1.78 – 4.58) with forceps and vacuum use respectively compared to spontaneous delivery. They identified other risk factors as nulliparity, adjusted OR 2.13(95%CI 1.81 – 2.48); epidural use, adjusted OR 1.38(95%CI 1.07 – 1.77) and grade of operator (obstetrician vs FP) adjusted OR 2.38(95%CI 1.98 – 2.87).

1.11 Relationship between episiotomy rates and operator beliefs

Several studies have shown differences in approach to episiotomy use between operators dependant on their beliefs about the benefits of episiotomy. Wilkerson (1984) studied the episiotomy rates of 21 midwives in an English hospital and concluded that the variation

could not be accounted for in clinical terms alone but was determined by which carer was involved. This variation in approach to episiotomy use in clinical practice is not restricted only to midwives at normal birth but also applies to obstetricians, whose practice includes the conduct of OVDs. Howden et al. (2004) showed a significant difference in episiotomy use between private and academic practitioners, adjusted OR 7.1(95%CI 6.5 – 7.7) as did Robinson et al. (2000) who also identified the professional group and place of practice as the most significant factors associated with the likelihood of an episiotomy being performed at vaginal delivery – midwives episiotomy rate was 21.4%, faculty members 33.3% and private providers 55.6%. Allen and Hanson (2005) found that, in similar low risk women, episiotomy was performed by obstetricians in 54% of cases and 33% of cases by family physicians ($p<0.001$). Gossett and Dunsmoor (2008) reported practitioner characteristics to be most predictive of episiotomy use with rates increasing the more remote the practitioner was from training or if the delivering physician was not the one providing antenatal care to the woman.

Klein et al. (1995) produced evidence that operators' beliefs can influence patient outcomes. Based on data from their RCT they reported that women attended by an operator who regarded episiotomy use as positive were more likely to have significant perineal trauma, perineal pain, lithotomy position for delivery, augmentation of labour, a shorter labour and less satisfaction with their birth experience than women attended by an operator who views episiotomy use as negative. They also found that practitioners with a positive view of episiotomy use were less likely to be willing to randomise participants within their RCT. These findings may have relevance to the conduct of the proposed study for this thesis and so merited further exploration in the formative work.

1.12 Episiotomy use at spontaneous vaginal delivery

Since the early 1980s the traditional rationale behind the routine use of episiotomy in SVD has been questioned leading to a rigorous evaluation of its usage. The seminal review by Thacker and Banta (1983) on the risks and benefits of episiotomy concluded that "little research has been done to test for benefit of the procedure and no published study can be considered adequate in its design and execution to determine whether hypothesized benefits do in fact result". The effect of this paper was to stimulate further high quality research which has resulted in considerable evidence for the adoption of a more restrictive approach to episiotomy use in SVD

Woolley (1995a; 1995b) performed a follow on review of the literature on the "Benefits and risks of episiotomy 1981 - 1994". He reported on five RCTs all of which are described in more detail in a systematic review by Carroli and Belizan (1999) discussed below. He concluded that episiotomy failed to protect the recipient from any of the morbidities it was thought to traditionally– perineal damage or pelvic floor relaxation and their sequelae or protection of the newborn from intracranial haemorrhage or intrapartum asphyxia whilst increasing the risk of severe perineal trauma, maternal blood loss, healing complications and perineal pain.

Carroli and Belizan (1999) performed a Cochrane systematic review of six RCTs entitled "Episiotomy for vaginal birth", comparing a routine use of episiotomy versus a primarily restrictive use of episiotomy (only where clinically indicated). The restrictive use of episiotomy was found to be associated with a lower risk of posterior perineal trauma (RR 0.74, 95% CI 0.71 – 0.77), less need for suturing perineal trauma (RR 0.74, 95% CI 0.71 – 0.77) and healing complications at seven days (RR 0.69, 95% CI 0.56 – 0.85) but, in contrast to Woolley (1995a; 1995b), was associated with an increased risk of anterior perineal trauma (RR 1.79, 95% CI 1.55 – 2.07). Although underpowered to distinguish

differences between rates of extensive perineal tears, all except two trials reported more anal sphincter tears in the routine use group. No differences were found in the incidence of dyspareunia or urinary incontinence (UI). Carroli and Belizan (1999) therefore concluded that the evidence base did not support the protective benefits for the mother traditionally ascribed to this intervention.

All trials included in this review used mediolateral episiotomy with the exception of Klein et al. (1992), a Canadian trial which used midline episiotomy which is more the norm in North America.

The Argentine trial (Argentine Episiotomy Trial Collaborative Group, 1993) was the largest of the trials with 2606 participants. Sleep et al. (1984) randomised 1000 women and Klein et al. (1992) had 703 participants with an uncomplicated labour and cephalic presentation at term. The remaining three trials were small with 200 or fewer participants each.

Five of the six trials reported random allocation of the treatment and concealment of the assignment by opaque envelope to reduce the risk of selection bias at entry to the trial. Only one trial (Harrison et al. 1984) was unclear about treatment allocation raising concerns in this regard. Each trial included all women randomised in the initial analysis (intention to treat analysis) except House et al. (1986) who excluded women not available for follow up at three days postpartum. This methodological flaw weakens the results of this trial. There was a loss to follow-up in the longer term studies of up to 57% (Argentine, at seven months postpartum). Trials were heterogeneous in their methodologies regarding definitions of liberal and restrictive use of episiotomy (Table 1.2) which resulted in differing episiotomy rates across the trials in each of the study arms (Table 1.3).

Table 1.2 Instructions to delivering clinician for allocated groups

Authors	Liberal Use	Restrictive Use
Harrison et al., 1984	In all cases	Not unless considered medically essential by the accoucheur
Sleep et al., 1984	To try to prevent a tear	To try to avoid episiotomy
House et al., 1986	Standard current management	Not allowed specifically for prevention of tears
Argentine Group, 1993	In all cases	No episiotomy unless indicated by the status of the fetus
Klein et al.,1992	Try to avoid a tear	Try to avoid an episiotomy
Eltorkey et al.,1994	Perform episiotomy unless considered absolutely unnecessary	Only if considered necessary to prevent extensive perineal laceration or if suspected fetal distress

Table 1.3 Episiotomy rate in six RCTs by parity

Authors	Parity of participant	Liberal Use n=	Episiotomy n (%)	Restrictive Use n=	Episiotomy n (%)
Harrison et al., 1984	Nulliparous	89	89(100.0)	92	7(7.6)
Sleep et al., 1984	Nulliparous	219	147(69.1)	201	36(17.9)
	Multiparous	283	111(39.2)	297	15(5.1)
House et al., 1986	Nulliparous	50	40(80.0)	50	16(32.0)
	Multiparous	23	11(47.8)	44	1(2.3)
Argentine Group,1993	Nulliparous	778	Nr(90.7)	777	Nr(39.5)
	Multiparous	520	Nr(70.5)	531	Nr(16.3)
Klein et al., 1992	Nulliparous	183	149(81.4)	173	99(57.2)
	Multiparous	116	78(47.0)	176	54(30.7)
Eltorkey et al., 1994	Nulliparous	100	83(83.0)	100	53(53.0)

Maternal outcome measures in the review included perineal trauma, including anterior and vaginal tears, need for surgical repair of tears, perineal pain, haematoma and healing complications such as infection or wound dehiscence in the early postpartum period. Two trials looked at the longer term morbidities of dyspareunia, time to resumption of sexual activity and UI up to three years after delivery. Neonatal outcome measures were low Apgar scores and admission to neonatal intensive care.

Another systematic review was conducted by Hartmann et al. (2005) which included one additional trial by Dannecker et al. (2004). Results of their review were comparable with Carroli and Belizan's findings in support of the restrictive use of episiotomy. Again, anterior tears were found to be more common in the restrictive group although they were associated with less need to suture perhaps indicating they were not as severe as posterior tears; intact perineum was uniformly less common in the routine compared with the restrictive use group (RR 0.46; 95%CI, 0.30 – 0.70); less suturing was required with a restrictive use of episiotomy and less pain and healing complications were experienced.

Hartmann's review identified one trial (Coats et al. 1980), which made a comparison between midline and mediolateral episiotomy. This single trial provided weak evidence suggesting that complications of midline episiotomy are greater than mediolateral episiotomy due to an increased risk of anal sphincter injury. Health care practitioners attending births in the United States are however likely to have greater experience performing midline than mediolateral episiotomy and both Carroli et al. (1999) and Hartmann (2005) cautioned against a shift to an unfamiliar technique until further evidence is available, the latter suggesting a more restrictive use of episiotomy might avert a larger number of all types of perineal injuries than change in technique.

Carroli's most recent update of their Cochrane review (2009) includes a further trial. Rodriguez et al. (2008) performed an RCT in Colombia comparing a routine use with a

selective use of midline episiotomy at vaginal delivery. Routine use was defined as all cases, selective use was only in cases of forceps delivery (no vacuum was used in their hospital), shoulder dystocia, fetal distress or impending severe tearing. The episiotomy rate was 100% and 24.3% in the routine and selective arms respectively. Routine use was found to increase the rate of third degree tears significantly (9.9% routine use vs 4.5% selective use; RR 2.19, 95%CI 1.06 – 4.52) however there was only a small but non significant increase in the rate of fourth degree tears (4.5% vs 2.3% respectively, RR 1.99, 95% CI 0.69 – 5.7). As in the previous studies anterior tears were significantly more common in the selective group.

In SVD this evidence base has supported the issue of policy statements and clinical guidelines by governmental and professional bodies for a restrictive approach to episiotomy use to be adopted. The World Health Organisation (WHO) (WHO 2002) states that routine use of episiotomy for normal vaginal birth is no longer recommended and that episiotomy should only be routine in the cases of:

- complicated vaginal delivery (breech, shoulder dystocia, forceps, vacuum)
- scarring from female genital cutting or poorly healed third or fourth degree tears
- fetal distress

1.13 Episiotomy use at operative vaginal delivery

While there is evidence to support a restrictive approach to episiotomy at spontaneous delivery, as described in the previous section, no such evidence exists for episiotomy use at OVD. Glazener (Henderson and Bick 2005) describes data from a survey of postnatal care completed as the basis of her PhD thesis. Eighty eight per cent of respondents having an OVD had an episiotomy performed compared to 19% who had a spontaneous delivery.

Whilst this finding is supported by other studies (Robinson et al. 1999; Bodner-Adler et al. 2003; Johnson et al. 2004; Youssef et al. 2005 and de Leeuw et al. 2008) OVD without the use of episiotomy has crept in to practice without rigorous formal evaluation (Helwig et al. 1993; Ecker et al. 1997; Kudish et al. 2006; Baskett et al. 2008).

In the literature search no RCTs of episiotomy use exclusively at OVD were identified. House et al. (1986), in a subgroup analysis with very small numbers, reported 22% of primiparae undergoing forceps delivery allocated to a liberal use of episiotomy sustained a third degree tear (due to an extended episiotomy) compared to none allocated to a restrictive use of episiotomy. They noted that no conclusions could be drawn from their study about the role of episiotomy at OVD but that further research was required in this area. This recommendation was further supported by Carroli and Belizan (1999) in their conclusions regarding the implications of their work for future research. They concluded that several questions remain unanswered about episiotomy use at vaginal delivery including the identification of indications for the restrictive use of episiotomy at OVD and that further trials were needed to address them.

Several cohort studies have been conducted investigating episiotomy use at OVD. Most of these studies are small retrospective studies and should be interpreted with the methodological limitations of this type of study. Studies with a prospective design may be less open to criticism in relation to selection bias than retrospective cohort studies where the argument could be made that the more severe cases resulted in increased trauma but still this methodology has limitations (Table 1.4). It may be that episiotomy is more frequently employed at complex deliveries which may be more associated with morbidity. Robust evidence would be provided by an RCT however in the absence of this level of evidence consideration must be given to the evidence provided by the cohort trials conducted to date.

Table 1.4 Characteristics of cohort studies of episiotomy use at OVD

Study author	Study design	n=	Episiotomy type	Episiotomy rate	
				vacuum	forceps
Ecker et al., 1997	Prospective	2041	1984 Midline Mediolateral 97% 3% 1994 Midline Mediolateral 74% 26%	1984 88.9% 1994 39.4%	1984 95.8% 1994 30.3%
Baskett et al., 2000	Prospective	1000	Not reported	48%	n/a[1]
Coombs, 1990	Retrospective	2832	Midline Mediolateral 71% 29%	Combined OVD 94%	
Helwig et al., 1993	Retrospective	392	Midline 100%	51.6%	36.2%
Robinson et al., 1999	Retrospective	323	Midline 97%	80.1%	85.2%
Johnson et al., 2004	Retrospective	508	NR[2]	81.8%	90.5%
Kudish et al., 2006	Retrospective	2505	Midline 99%	42.5%	38.3%
Bodner Adler et al., 2003	Retrospective	87	Midline Mediolateral 36% 64%	n/a	87%
Youssef et al., 2005	Retrospective	2153	Mediolateral 100%	71.4%	95.8%
Hudelist et al., 2005	Retrospective	333	Mediolateral 100%	n/a	NR[2]
De Leeuw et al., 2008	Retrospective	28,732	Midline Mediolateral 8% 92%	79.5%	90.1%

1 not applicable (n/a)

2 not reported (NR)

Ecker et al. (1997) performed a time series analysis, obtaining data from 2041 consecutive OVDs over a ten year period in San Francisco. Using linear regression they compared yearly rates of episiotomy with rates of perineal tears and potential confounders. The episiotomy rate fell significantly from 93.4% in 1984 to 35.7% in 1994 ($p=0.0001$). There was significant increase in the rate of intact perineum at OVD, 2.2% to 2.7%, $p<0.05$. This was associated with no significant change in the third degree tear rate over the study period but a significant increase in the rate of vaginal tears (16.1% to 40.0%, $p=0.0002$) and a significant decrease in the rate of fourth degree tears (12.2% to 5.4%, $p=0.004$). An examination of potential confounders (nulliparity, birth weight > 4kg, Asian race, station and position of the fetal head and instrument used) revealed only instrument use had changed significantly over the study period. Results were similar even after stratifying for parity and instrument used. Whilst this change in policy regarding episiotomy use at OVD appears to have been instigated in the absence of evidence to support it, results of this study would suggest that episiotomy may be protective of anal sphincter tearing especially fourth degree tears.

Baskett et al. (2008) studied 1000 vacuum assisted deliveries prospectively in a Canadian cohort from 2002-2005. The aim of this study was to establish the maternal and perinatal outcomes associated with delivery assisted by the Omnicup vacuum device which had recently been introduced to their hospital. A comparison of anal sphincter tearing with and without episiotomy use revealed a significantly greater likelihood of tearing with episiotomy use - more pronounced for nulliparous women (17.2% vs 7.9%, $p< 0.001$) than multiparous women (9.5% vs 2.8%, $p=0.02$).

Combs et al. (1990) studied 2832 consecutive OVD retrospectively between 1975 and 1988 in the US. They found midline episiotomy to be the strongest predictor of anal sphincter tearing [adjusted OR 7.8, (95% CI 5.9 – 10.3)] followed by nulliparity [adjusted

OR 3.6, (95% CI 2.7 – 4.7)] and forceps delivery versus vacuum [adjusted OR 1.9, (95% CI 1.5 – 2.5)].

Helwig et al. (1993) explored the relationship between midline episiotomy and severe perineal trauma at OVD in a retrospective cohort study (n=392) in the US over a one year period (1989-90). Episiotomy, birth weight and whether the index birth was a first vaginal birth were found to be associated with third and fourth degree perineal tearing. In their cohort 48.5% of primiparae delivering a baby of ≥ 3500g in whom an episiotomy had been performed suffered a third or fourth degree tear. After adjusting for parity and birth weight, episiotomy was found to have an RR of 2.4(95% CI 1.7-3.5) for anal sphincter tearing. Findings were the same for forceps (n=268) and vacuum (n=124) deliveries.

Robinson et al. (1999) performed a retrospective cohort study, of 323 consecutive OVDs among nulliparous women at an American centre, to establish the relationship between instrument choice and severe perineal trauma and to assess whether this rate was modified by the use of episiotomy. The rate of episiotomy was 129/161(80%) at vacuum extraction deliveries and 138/162(85%) at forceps deliveries. There was a significantly higher rate of severe perineal trauma among women delivered by vacuum with episiotomy compared to women delivered by vacuum without episiotomy (34.9% vs 9.4%, p=0.005). However at forceps delivery there was no significant difference in the rate of severe perineal trauma with or without episiotomy (55% vs 45.8%, p=0.4). They concluded that, whilst there were no differences in the rate of significant perineal trauma according to the type of forceps employed or the use of episiotomy at forceps deliveries (RR 1.2, 95% CI 0.8 - 1.9), there was a significantly increased risk of such trauma in vacuum extraction where episiotomy was employed (RR 3.7, 95% CI 1.2 - 11.2).

Johnson et al. (2004) performed a retrospective cohort study over a 20 month period in the US. They reviewed 508 deliveries (200 forceps and 308 vacuum assisted) to assess the

maternal and neonatal complications of OVD. The incidence of episiotomy use at forceps assisted deliveries was found to be significantly greater than at vacuum assisted deliveries (OR 2.12, 95%CI 1.18 – 3.83). Analysis by instrument combined with episiotomy revealed no significant differences in the rate of third degree tears (27.4% vacuum vs 33.7% forceps, p=0.16) however the fourth degree tear rate was significantly higher with the use of forceps combined with episiotomy (4.8% vs 12.2%, p=0.005). Periurethral tears were more frequent in vacuum deliveries even when episiotomy was performed which would question its protective role. On multivariable logistic regression, forceps delivery and episiotomy were both found to be independently associated with severe perineal and vaginal tears, (OR 1.85, 95%CI 1.27 – 2.70 and OR 2.22, 95%CI 1.22 – 4.05 respectively).

Kudish et al. (2006) studied the impact of OVD with midline episiotomy on the risk of anal sphincter tearing. This retrospective cohort study was set in Canada over a seven year period (1996-2003). Of a total cohort (n=2505; 1703 forceps assisted deliveries, 802 vacuum extractions), 994(39.7%) had an episiotomy performed (38.3% of forceps deliveries and 42.5% of vacuum extractions). Whilst not explicitly stated in their paper, these numbers would suggest a restrictive approach to episiotomy use at OVD was being employed in this hospital. Among nulliparous women, 39.3% sustained a third or fourth degree tear when episiotomy was performed compared to 18.3% when no episiotomy was performed (p<0.001). Likewise, of multiparous women at OVD, 24.7% had severe perineal trauma with episiotomy compared to 6.5% without (p<0.001). On subgroup analysis by instrument the authors reported in nulliparous women, both forceps and vacuum in combination with episiotomy increased the risk of severe anal sphincter tearing substantially when compared to spontaneous delivery [Forceps combined with episiotomy (OR 21.1, 95%CI 16.7 – 25.5) compared with forceps and no episiotomy (OR 8.6, 95%CI

6.6 – 10.7) and vacuum combined with episiotomy (OR 13.7, 95%CI 10.1 – 17.3) compared with vacuum and no episiotomy (OR 3.1, 95%CI 1.9 – 4.3)]. A similar picture is seen in multiparae [forceps combined with episiotomy (OR 77.1, 95%CI 49.7 – 104.5) compared with forceps and no episiotomy (OR 26.3, 95%CI 18.1 – 34.5) and vacuum combined with episiotomy (OR 123.5, 95%CI 71.1 – 175.9) compared with vacuum and no episiotomy (OR 1.2, 95%CI 0.1 – 2.3)]. An explanation of this may be a greater complexity to deliveries in which episiotomy was performed compared to those in which it was not deemed necessary, however, this data was not provided in the paper.

These studies all question the belief that episiotomy is protective for severe perineal trauma at either forceps or vacuum extraction. The results however, should be interpreted in the context of predominantly midline episiotomy and may not be applicable to mediolateral episiotomy as practised most commonly in the UK and Europe. Several studies have been conducted in Europe where the use of mediolateral episiotomy is more prevalent.

Bodner-Adler et al. (2003) conducted a small (n=87) retrospective cohort study of all forceps deliveries in a single site in Vienna, Austria over a six month period to evaluate the relationship between episiotomy use and the frequency and severity of perineal trauma. The approach to episiotomy use at this hospital was restrictive, the decision whether or not to perform an episiotomy being left to the delivering clinician. Episiotomy was however performed in 76/87(87%) of their forceps assisted deliveries (64% mediolateral, 36% midline). The rate of anal sphincter tearing reported was 3/11(27%) of forceps deliveries without episiotomy versus 4/76(5%) of such deliveries with episiotomy. Furthermore, they found that perineal trauma of all degrees was significantly less in forceps deliveries when episiotomy was performed (12% with episiotomy vs 82% without episiotomy, $p< 0.001$) On further analysis by type of episiotomy, mediolateral episiotomy was found to be more

protective against severe perineal trauma in women undergoing a forceps assisted delivery than midline episiotomy (2% vs 11%, p=0.007). These findings were in contrast to those of Robinson (1999) who found no differences in rates of significant perineal trauma at forceps delivery performed with or without episiotomy and the other American studies which found episiotomy to bestow no protection in respect of perineal tearing and indeed to perhaps contribute to it.

Youssef et al. (2005) performed a retrospective population based cohort study of 2153 women who experienced an OVD over a five year period between January 1998 and December 2002 in the authors' hospital. The aim of this study was to investigate the maternal and neonatal morbidity related to the use of episiotomy in these deliveries. Eighty nine per cent of women experienced episiotomy (71.4% of vacuum extractions and 95.8% of forceps assisted deliveries). Episiotomy use was associated with nulliparity, birth weight, prolonged second stage of labour, and fetal malposition. Results showed extensive perineal tears were more likely with episiotomy use (7.5% vs 2.5%, adjusted OR 2.92, 95% CI 1.27 - 6.72) as was neonatal trauma (6.0% vs 1.7%, adjusted OR 2.62, 95% CI 1.05 - 6.54). Episiotomy however did not reduce the incidence of shoulder dystocia (adjusted OR 1.43, 95% CI 0.74 - 2.76). In conflict with Robinson's study, these findings were similar for delivery by vacuum and forceps.

Another small retrospective cohort study was conducted in Austria by Hudelist et al. (2005) including 333 vaginal deliveries assisted by obstetric forceps over a five year period (1999 – 2003). Episiotomy was routinely performed at OVD in their institution. It established that 14(4.2%) of women sustained an anal sphincter tear. In multivariate regression models only high birth weight (OR 1.68, 95%CI 1.18 – 2.41) and forceps delivery combined with mediolateral episiotomy (OR 5.62, 95%CI 2.16 – 14.62) proved to be independent risk factors for anal sphincter tears compared to spontaneous delivery.

de Leeuw et al. (2008) carried out a large population based retrospective study in the Netherlands between 1994 and 1995. Their cohort (n=28,732) derived from the Dutch National Obstetric Database. 21,254 had delivered with vacuum and 7478 with forceps. Anal sphincter tears occurred in 3.0% of vacuum extractions and 4.7% of forceps deliveries. They found that mediolateral episiotomy was highly protective for anal sphincter tearing both at vacuum (OR 0.11, 95% CI 0.09 – 0.13) and forceps delivery (OR 0.08, 95% CI 0.07 – 0.11).

The current evidence in respect of the relationship between anal sphincter tearing and episiotomy use at OVD is inconclusive (Table 1.5). Studies to date however have been cohort (retrospective and prospective) with the possibility of biases inherent to these methodologies. These findings support the need for a more robust exploration of this relationship by the conduct of an RCT to better inform clinical practice in respect of the approach to episiotomy use at such deliveries.

Table 1.5 Summary of the relationship between episiotomy use and the risk of anal sphincter tears by instrument in cohort studies

	Forceps delivery	Vacuum delivery
Combs, 1990	Increases risk ɵ	Increases risk ɵ
Helwig et al., 1993	Increases risk	Increases risk
Ecker et al., 1997	Increases risk*	Increases risk*
Robinson et al., 1999	No difference	Increases risk
Baskett et al., 2000	n/a	Increases risk
Johnson et al., 2004	Increases risk*	No difference
Kudish et al., 2006	Increases risk	Increases risk
Bodner Adler et al., 2003	Decreases risk	n/a
Youssef et al., 2005	Increases risk	Increases risk
Hudelist et al., 2005	Increases risk	n/a
De Leeuw et al., 2008	Decreases risk	Decreases risk

ɵ no differentiation by instrument

* fourth degree tears only

1.14 Variation of episiotomy rate at vaginal delivery

No consensus has emerged about what an acceptable level of episiotomy rate should be at SVD. The Argentine Episiotomy Trial Collaborative Group (1993) in their RCT recommended less than 30% but this has been suggested as too high by other commentators who cited a rate of 20% as perhaps a more appropriate level based on rates achieved in their trials where selective use of episiotomy use was employed in specific circumstances (Henriksen et al. 1992, Weber and Meyn 2002).

Following review of the literature with regard to episiotomy use it is clear that episiotomy rates have varied with time and place for vaginal delivery. No studies were identified which explored the differences in rates of episiotomy use exclusively at OVD.

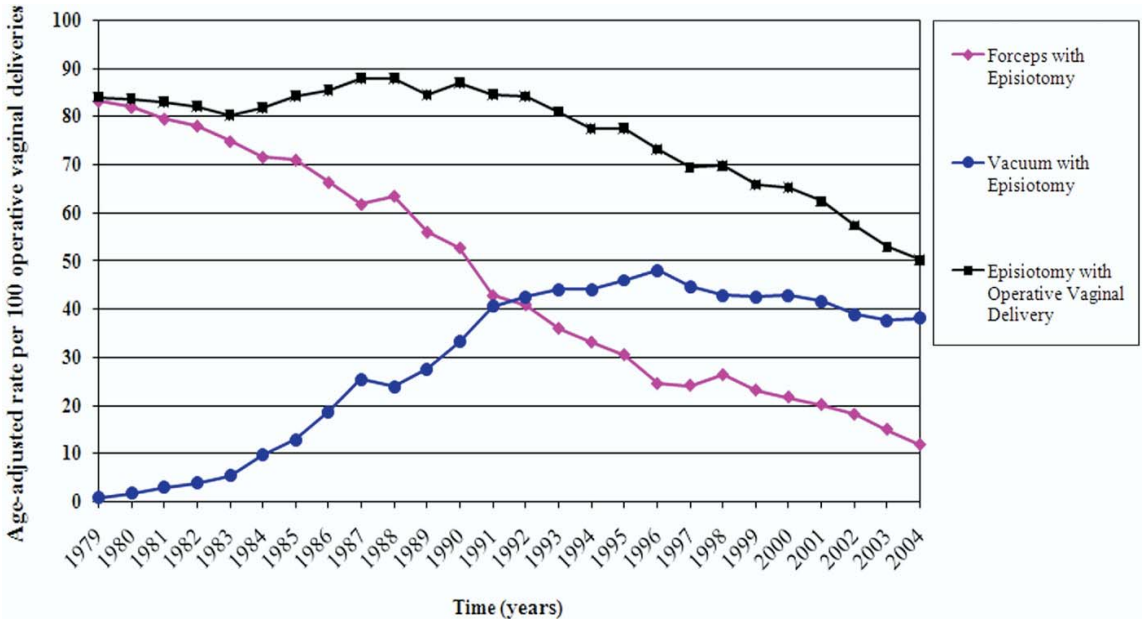
Williams et al. (1998) presented findings of a survey of 101 larger obstetric units across the UK over a 12 month period from February 1993. They found a regional variation in episiotomy rates from 26% to 67%. This survey preceded the introduction of national policy regarding episiotomy use at vaginal birth reflecting the controversy amongst practitioners at that time.

Translation into practice of the increasing evidence from trials, culminating in the introduction of the WHO guidelines, has led to a considerable decline in the rate of episiotomy use at vaginal birth in some countries.

The survey of obstetric practices by Alran et al. (2002) in nine tertiary referral hospitals in Europe between November 1999 and October 2000 reported a variation in the rate of episiotomy use at vaginal delivery from 9.7% in Uppsala to 58% in Perugia.

Weber and Meyn (2002) used the National Hospital Discharge Survey to describe episiotomy use at vaginal delivery in the US between 1979 and 1997. They described a significant decrease in the percentage of spontaneous deliveries with episiotomy over this time period from 60% to 33%. Episiotomy rates at OVD also interestingly decreased from 87% to 71% over this time scale despite a paucity of evidence on which to base this change in practice. Most of this decrease at OVD was in the five year period 1993 – 1997. There is evidence from Frankman et al. (2009) that this decline has continued (Figure 1.12).

Figure 1.12 Age adjusted rates of episiotomy per 100 operative deliveries in the US 1979 – 2004



Source Frankman et al. (2009)

Kozak and Weeks (2002) using the same database reported the fall in episiotomy rates in the US following guideline introduction with a concomitant rise in the suturing of first and second degree tears but a decrease in the suturing of extensive perineal tears which would support the correlation between episiotomy use and extensive perineal damage.

Graham et al. (2005) presented an update to episiotomy rates around the world and concluded that, despite international acceptance of evidence supporting a restrictive approach at spontaneous vaginal birth, rates continue to vary between countries, within countries and indeed within operator groups. They reported rates varied from 10% in Denmark, 13% in England and 16% in Scotland in 2002-2003 to an estimated 100% in Taiwan.

Globally then, practice does not appear to reflect policy statements and clinical guidelines for a restrictive approach to episiotomy at SVD issued by the WHO, American and UK Colleges of Obstetricians & Gynaecologists and many other governmental and professional

bodies. There would seem to be a discrepancy between rates in Europe and North America, which have reduced significantly and developing countries where the recommendations are yet to impact.

1.15 Maternal Morbidities Associated With Operative Vaginal Delivery and Episiotomy

When OVD is indicated in the second stage of labour, both the choice of instrument and the decision whether to perform an episiotomy may affect the potential for maternal perineal injury and neonatal trauma (Robinson et al. 1999). Short-term complications of perineal injury include pain, infection and haemorrhage (Johanson and Menon 1999). Long-term effects include dyspareunia, incontinence of urine, and incontinence of flatus or faeces (MacArthur et al. 2001; Liebling et al. 2004).

1.15.1 Urinary Incontinence

Urinary incontinence (UI) is the complaint of any involuntary leakage of urine (Abrams et al. 2003). For the purposes of this thesis, UI is described by symptoms, elicited from participants, which are experienced during the storage phase of the bladder and is defined according to the standardisation of terminology by the International Continence Society which may include:

- Frequency – the complaint by the participant who considers that she voids too often by day
- Urgency - the complaint of a sudden compelling desire to pass urine which is difficult to defer
- Stress UI - the complaint of involuntary leakage on effort or exertion, or on sneezing or coughing

- Urge UI - the complaint of involuntary leakage accompanied by or immediately preceded by urgency

UI should be explored further by attempting to describe how often it occurs, severity, effect on quality of life (QOL) and the measures used to contain the leakage.

UI is known to be a common and distressing problem following childbirth which may persist for the long term. Many studies have tried to quantify the prevalence of this debilitating sequel to vaginal birth and to identify the main risk factors associated with it. The incidence of de novo postnatal UI has been reported in up to 56% of women (Wesnes et al. 2009). Glazener et al. (2001) observed that three months after delivery 30% of women irrespective of mode of delivery reported UI and similarly, Chiarelli and Cockburn (2002) reported a rate in excess of 30% in their cohort of women eight weeks after an OVD or delivery of a macrosomic neonate (birth weight >.4000g). Viktrup and Lose (2001) demonstrated that stress incontinence may occur five years after a first delivery especially if incontinence was reported three months after delivery.

1.15.1.1 Relationship between UI and OVD

Studies using ultrasound and magnetic resonance imaging (MRI) have shown a significant association between OVD and injury to the levator ani. Krofta et al. (2009) used introital 3D/4D ultrasound to assess the effects of forceps assisted delivery on the levator hiatus and found avulsion of the pubovisceral muscle to be more common 12 months after forceps assisted vaginal delivery than SVD. The resultant hypothesis is that during OVD tissues extend more rapidly than at SVD causing excessive stretching of muscles and nerves and a resultant increase in damage. It is however not clear as to whether it is the action of the OVD that causes the damage or the indications present which necessitate assisted delivery.

Liebling et al. (2004) conducted a prospective cohort study of 393 women at term with a singleton, cephalic, pregnancy that required delivery in the second stage of labour either by OVD or CS. They concluded that OVD was associated with a greater risk of UI at six weeks (OR 7.80, 95% CI 2.58 - 23.55) and one year postpartum (OR 3.12, 95% CI 1.27 - 7.64) than a CS at full dilatation. Follow-up work on this cohort at three years postpartum by Bahl et al. (2005) revealed a persistent increased risk of UI. Wesnes et al. (2009) however conducted a retrospective cohort study in Norway of 12,679 primiparae who were continent before pregnancy. Forty per cent of women reported some degree of UI at 30 weeks gestation and in 48% of these women UI persisted at six months postpartum. Their analysis of the impact of mode of delivery revealed little difference between spontaneous and assisted vaginal deliveries (34%; adjusted RR 3.2, 95%CI 2.5 – 3.9 for SVD; 36%; adjusted RR 3.3, 95%CI 2.6 – 4.0 for vacuum extraction and for forceps 37%; adjusted RR 3.5, 95%CI 2.6 – 4.3). Likewise a comparison of those who were continent in pregnancy compared to those who reported antepartum incontinence by mode of delivery revealed a greater likelihood in all modes of delivery in women with antepartum incontinence but little difference comparing modes of delivery. Significant differences were seen in continence status at 30 weeks gestation with women more likely to be incontinent postpartum if they had reported ante partum de novo incontinence (Table 1.6).

Table 1.6 Urinary incontinence six months postpartum by continence status during pregnancy and mode of delivery

	Continent during pregnancy	RR(95%CI)	De novo incontinence in pregnancy	RR(95%CI)
SVD	1166(23%)	3.2 (2.1 – 4.7)	1837(51%)	2.9 (2.3 – 3.4)
Vacuum	250(26%)	3.2 (2.1 – 4.6)	337(56%)	3.1 (2.4 – 3.6)
Forceps	55(30%)	4.0 (2.6 – 5.8)	58(50%)	2.8 (2.0 – 3.4)

Source: Wesnes, 2009

These results broadly agreed with previous studies (Glazener et al. 2006). Evidence suggests therefore that vaginal delivery of any mode poses a greater risk of postpartum UI than CS but that OVD carries no greater risk than SVD.

1.15.1.2 Relationship between UI and anal sphincter tears

Research evidence suggests that there is no correlation between anal sphincter tearing and the incidence of postpartum UI. A prospective cohort study by Borello-France et al. (2006) found there was no difference in the prevalence of UI in women with an anal sphincter tear compared to women without at either six weeks or six months postpartum. At six weeks, 34.8% of women experiencing an anal sphincter tear reported UI vs 35.4% of women without a tear (p=0.76) and at six months 33.7% vs 31.3% respectively (p=0.66). These findings were similar to those of Otero et al. (2006) who assessed women 18 years after delivery who had sustained an anal sphincter tear. They reported 22% of women with an anal sphincter tear had urinary symptoms vs 19% without a tear (RR 1.2, 95%CI 0.8 – 1.6).

1.15.1.3 Relationship between UI and episiotomy

The role of episiotomy in the prevention of UI has been addressed in several studies. Hartmann et al. (2005), in a systematic review of the outcomes of routine episiotomy, concluded that there was no evidence to support episiotomy to preserve of continence of urine up to four years after birth. Episiotomy and spontaneous tear groups had the same frequency of incontinence symptoms (RR for trials (n=2) 1.02; 95%CI 0.83 – 1.26; RR for cohort studies (n=4) 0.88; 95%CI 0.72 – 1.07)

This review comprised two RCTs. The first, Sleep et al. (1984) found that 19% of women (22% multiparae, 15% primiparae) in both the routine and restrictive episiotomy arms of their study had involuntary loss of urine three months after delivery (RR1.00, 95%CI 0.76 – 1.30) which provided no evidence that a routine use of episiotomy would protect against this problem. Similarly, no differences were found between the two study arms with regard to the need to sometimes wear a vulval pad (5.4% restrictive use vs 5.2% liberal use). A follow-up questionnaire study at three years after delivery (Sleep and Grant 1987) found UI was again equally reported between the two groups. At this time point, 34% of women allocated to a restrictive use of episiotomy reported they had involuntarily lost urine vs 36% of women allocated to a routine use of episiotomy (RR 0.97, 95%CI 0.79 – 1.19). Secondly, Klein et al. (1992) who supported the findings of Sleep (1984) with no differences found between study arms in their trial which employed midline episiotomy.

In addition to the two RCTs discussed, Hartman et al. (2005) included four prospective cohort studies in their systematic review of the outcomes of episiotomy with regard to UI. Eason et al. (2004) investigated risk factors associated with UI three months after delivery among 949 women in Canada. Like others (Wesnes et al. 2009; Glazener et al. 2006) they found that UI at three months postpartum is associated with pre-pregnancy incontinence (adjusted OR 6.44, 95%CI 4.15 – 9.98) and de novo ante partum incontinence (adjusted

OR 1.93, 95%CI 1.32 – 2.83). They found a trend towards increasing incontinence with forceps delivery (OR 1.73, 95%CI 0.96 – 3.13) and towards a protective role for episiotomy use at delivery with regard to UI at three months postpartum (29% with episiotomy vs 35% without, adjusted OR 0.68, 95%CI 0.47 – 1.01) neither of which however were statistical significant. Sartore et al. (2004) compared 254 women who delivered with episiotomy with 265 without three months postpartum to identify the incidence of stress incontinence. In contrast to the study by Eason et al. (2004) they found that women delivered without the use of episiotomy were significantly more likely to be completely asymptomatic at three months postpartum (p=0.011). However like Eason et al. (2004) they found no difference between the groups for stress incontinence (12.9% with episiotomy vs 12.1% without, OR 1.01, 95%CI 0.61 – 1.69), urge incontinence (1.9% with episiotomy vs 0.7% without, p=0.23) or frequency and urgency (0.8% with episiotomy vs 2.3% without, p=0.17). Karaçam and Eroğlu (2003) conducted a small study in Turkey comparing 50 women delivered with episiotomy with 50 delivered without. Concurring with the others two studies described here they found no differences in the incidence of stress incontinence between women delivered with and without episiotomy up to three months postpartum 12% vs 15% respectively, p=0.499. Further support was provided by Rockner (1990) who found no significant differences between women with (n=140) and without (n=42) episiotomy four years after delivery

A quasi randomised comparative study was conducted in two French hospitals, one with a routine approach to episiotomy for primiparae and one with a restrictive approach (Fritel et al. 2008). Follow up was four years after delivery. There were no significant differences between the two institutions in respect of the incidence of UI (all UI 32% vs 26% p=0.09; stress incontinence 31% vs 29%, urge incontinence 6% vs 7%, mixed incontinence 59% vs 62%, p=0.67).

In contrast to this evidence Casey et al. (2005) present findings from their prospective cohort study suggesting both forceps delivery (OR 2.1, 95%CI 1.3 – 3.5) and episiotomy (OR 1.7, 95%CI 1.3 – 2.4) are risk factors for urge incontinence but not stress incontinence in primiparae up to seven months postpartum. These disparate findings may be accounted for in methodological limitations in the study. The study population accounted for less than 30% of the total cohort and only included women who returned to their hospital to access contraception services resulting in obvious selection bias. This bias, one may hypothesise, may in fact minimise their findings as women experiencing UI score significantly less well on sexual function questions (Dean et al. 2008) and so the worst affected women may not have resumed sexual activity and be in need of contraception by this time point.

In conclusion the incidence of UI does not appear to be influenced by mode of vaginal delivery, anal sphincter tearing or the performance of an episiotomy. Although unlikely to be influenced by the approach to episiotomy use at OVD it requires to be investigated in an RCT.

1.15.2 Anal incontinence

Anal incontinence (AI) is defined as "the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem" by the International Continence Society (Norton et al. 2002). It is a challenging condition which may have a devastating social and economic cost for both the individual and society as a whole. Faecal soiling has been reported by up to 5% and involuntary loss of stool in up to 1.5% of the general population (Jorge and Wexner 1993) but as a source of social embarrassment it may be under reported. In the US faecal incontinence is the second most common cause of institutionalisation in the elderly and is eight times more common in middle aged women than men. This gender

imbalance has been attributed to childbirth by some commentators (Nichols et al. 2006; Fitzpatrick and O'Herlihy 2001).

1.15.2.1 Relationship between AI and OVD

Considerable attention has been paid in the literature to the relationship between mode of delivery and AI. Pretlove et al. (2008) conducted a systematic review comprising 18 studies to examine the association between mode of delivery and AI in the first year postpartum. This review concluded that compared to CS, vaginal delivery has a significantly higher risk of AI. Within vaginal delivery, OVD is more associated with AI than SVD (OR 1.32, 95%CI 1.04 – 1.68) and within OVD, forceps (OR 2.01, 95%CI 1.47 – 2.74) more than vacuum (OR 1.60, 95%CI 1.07 – 2.40). These findings were only significant where flatal incontinence was included. No significant differences were found between groups if only liquid and solid faecal incontinence were studied. Compared to SVD, only forceps was significantly associated with AI (OR 1.50, 95%CI 1.19 – 1.89). A comparison of forceps vs vacuum reports forceps delivery to be more significantly associated with AI (OR 1.51, 95%CI 1.07 – 2.13). The authors caution against over interpretation of these results as there was a high level of heterogeneity between the studies and poor methodological quality.

Studies included in Pretlove's systematic review include Liebling et al. (2004) who in their prospective cohort study as discussed earlier (chapter 1.12.6) found at least one symptom of bowel dysfunction to be reported by 57% of women but no significant differences between women delivered by OVD and CS in the second stage of labour. Unlike UI, symptoms of AI had improved by one year postpartum compared to six weeks postpartum. Bahl et al. (2005) in their follow up of this cohort comparing pelvic floor

symptoms three years after delivery found no significant differences in terms of ano-rectal symptoms.

Fitzpatrick et al. (2003) randomised 130 women who required an OVD to either a vacuum or low cavity non rotational forceps assisted delivery. Follow up was by questionnaire and endoanal ultrasound at three months postpartum. 59% of women complained of altered faecal continence after forceps delivery compared with 33% following vacuum extraction (RR 2.88, 95% CI 1.41 - 5.88). Endoanal ultrasound reported abnormality following 56% of forceps deliveries and after 34% of vacuum extractions. After exclusion for failed vacuum this difference was significant (p=0.004)

In a study by Sultan et al. (1993a) of primiparae undergoing OVD 38% of women following forceps delivery developed defecatory symptoms and 12% at vacuum delivery compared with two per cent at spontaneous delivery (p=0.003 and p>0.05 respectively).

1.15.2.2 Relationship between AI and anal sphincter tearing

Obstetrical anal sphincter tears are the principal but not sole cause of the development of AI in otherwise healthy females. Implications for the mother who has sustained anal sphincter tearing may include flatal and/or faecal incontinence which in some cases may be long term.

Studies have addressed the relationship between anal sphincter tearing and the development of AI and substantial evidence exists that anal sphincter tearing is a major risk factor for the development of AI. Eason et al. (2002) as part of an RCT investigating perineal massage in the third trimester of pregnancy, prospectively collected data on 1198 participants with a questionnaire sent three months postpartum to elicit symptoms of AI. A 79% response rate was achieved. Incontinence of stool occurred in 3.1% of women and 25.5% reported involuntary escape of flatus. Incontinence of stool was more frequent

among women who had third- or fourth-degree perineal tears compared to women with no perineal trauma [7.8% v. 2.8% respectively, RR 2.8(95%CI 0.8 – 9.6)]. They found forceps delivery and anal sphincter tearing to be independent risk factors for AI of flatus or stool or both and anal sphincter tearing to be strongly predicted by primiparity, median episiotomy and OVD.

Sultan et al. (1994) also reported defecatory symptoms in 47% of women following a repaired third degree tear (41% AI and 26% faecal urgency), compared with 13% in the control group. Anal sphincter defects were identified by anal endosonography in 85% of women with a third/fourth degree tear and 33% of the control group. The significance of these asymptomatic defects remains uncertain.

Borello-France et al. (2006) in their prospective cohort study found an increased risk of AI in the group with anal sphincter tearing compared to the vaginal control group without anal sphincter tearing at six weeks postpartum (OR 2.8, 95%CI 1.8 – 4.3) and at six months (OR 1.9, 95%CI 1.2 – 3.2). These findings persisted for flatal incontinence alone (OR 1.6, 95%CI 1.1 – 2.4 at six weeks and OR 1.7, 95%CI 1.1 – 2.7 at six months) and faecal urgency (OR 1.5, 95%CI 1.1 – 2.1 at six weeks and OR 1.5, 95%CI 1.02 – 2.2 at six months). They also reported a higher prevalence of both measures in women with a fourth degree tear compared to a third degree tear (faecal incontinence at six weeks 39% vs 23%, p=0.005 and six months 26% vs 15%, p=0.02 and faecal urgency at six weeks 49% vs 34%, p=0.02 and six months 43% vs 29%, p=0.02). Fenner et al. (2003) also found the incidence of worse bowel control to be almost ten times higher in women with a fourth degree tear compared to a third degree tear (30.8% vs 3.8% respectively, $p<0.001$)

Nichols et al. (2006) examined the relationship between degree of perineal tearing and AI in women delivered vaginally compared to women delivered by CS. New bowel symptoms

were reported by 39.1% of women delivered vaginally with a third or fourth degree tear compared to 4.8% of women delivered by CS (p=0.003) or 11.3% of women delivered vaginally with first or second degree tears (p=0.007). A significant association was also identified between bowel symptoms and the degree of anal sphincter injury compared to women without an anal sphincter tear [EAS defect only, OR 3.2 (95%CI 2.1 – 4.7), IAS only OR 10.1 (95%CI 4.5 – 22.6) and combined EAS and IAS defect OR 32.1 (95%CI 9.6 – 107)].

1.15.2.3 Relationship between AI and episiotomy

The role of episiotomy and its association with AI is less clear. No evidence is available from RCTs of episiotomy use at vaginal birth however one quasi randomised trial and several cohort studies have reported on the role of mediolateral episiotomy with regard to AI with a range of conclusions.

Fritel et al. (2008) in their quasi randomised study described earlier compared approach to episiotomy use with regard to incidence of AI. They reported that a policy of routine episiotomy was associated with a greater risk of AI compared to a restrictive policy (16% vs 11% if flatal incontinence is included). This significant difference persisted for flatal incontinence alone (8% vs 6% respectively) but not for faecal incontinence of stool (3% for both groups).

de Leeuw et al. (2001) in his retrospective case control study identified that mediolateral episiotomy was protective of faecal incontinence in primiparous women (OR 0.17, 95%CI 0.05 – 0.60).

The systematic review by Hartmann et al. (2005) (described chapter 1.15.2.2) concluded that episiotomy use almost doubled the risk of AI (RR1.91, 95%CI 1.03 – 3.56)

This review comprised three cohort studies. MacArthur et al. (1997) found no difference in the rate of AI when episiotomy was employed compared to spontaneous tearing in primiparae (4.6% vs 5.1% respectively) but in multiparae the use of episiotomy was strongly associated with the development of AI (8.8% vs 2.7%, p< 0.05). In Eason et al. (2002) (described chapter 1.15.2.2), episiotomy was identified to be a risk factor for the development of AI. AI was more common in women with episiotomy compared to those with a first or second degree tear (4.4% vs 2.3%, RR 1.9, 95%CI 0.7 – 4.8). The findings in the study by Sartore et al. (2004) described earlier (chapter 1.15.2.2) were similar to MacArthur et al. (1997) (AI incidence 2.8% vs 1.9% [epis vs no epis], OR 1.47, 95%CI 0.46 – 4.7).

It is evident from these observations that childbirth and in particular sustaining anal sphincter trauma, known to be more likely in OVD and episiotomy, is the main risk factor for faecal incontinence in the female population. The role of episiotomy per se is less clear and requires further investigation in an RCT.

1.15.3 Haemorrhage

Primary postpartum haemorrhage (PPH) is a blood loss of 500mls or more from the genital tract in the immediate postpartum period (first 24 hours after delivery) and remains a significant cause of maternal morbidity and mortality (Mouza and Alfirevic 2007). It is often a result of an atonic uterus but may be secondary to uterine, cervical and severe perineal injury which occurs most commonly as a result of OVD (Power et al. 2006). Risk factors identified in the RCOG Guideline on Prevention and Management of Postpartum Haemorrhage (Greentop guideline no. 52, RCOG press, 2009) include episiotomy (approximate OR 5, no CI reported) and OVD (approximate OR 2.0, 99%CI 1.56–2.07)

In a study by Sosa et al. (2009), episiotomy (16.2%, OR 4.67, 95%CI 2.41 – 9.05) and need for perineal suture (15.0%, OR 1.66, 95%CI 1.11 – 2.49) were identified as independent risk factors for PPH > 500mls. Only the need for perineal suture remained a significant risk factor associated with PPH > 750mls (2.5%, OR 2.50, 95%CI 1.87 – 3.36). Sheiner et al. (2005) identified lacerations and instrumental delivery as significant risk factors for PPH (OR 2.4, 95%CI 2.0 – 2.8 and OR 2.3, 95%CI 1.6 – 3.4 respectively). Demissie et al. (2004) reported vacuum extraction to be more significantly likely to lead to PPH than forceps deliveries OR 1.22 (95%CI 1.07 – 1.39) whereas Benedetto et al. (2007) reported the higher rate of haemorrhage to be associated with forceps assisted deliveries (1.8%) probably due to the high incidence of severe perineal, vaginal or cervical lacerations (7.3%). Baksu et al. (2008) conducted a case controlled study to investigate the effect of timing of episiotomy (both midline and mediolateral) repair on peripartum blood loss. They measured maternal haemoglobin and haematocrit at admission and 24 hours postpartum. The decrease in these measurements was significantly greater when an episiotomy was performed compared to no episiotomy suggesting a greater blood loss with episiotomy use. Timing of repair had no impact on blood loss when midline episiotomy was performed whereas mediolateral episiotomy was associated with significantly less bleeding if repaired before placental removal. Repair before placental delivery led to less blood loss in both midline and mediolateral episiotomy whereas a greater blood loss was associated with mediolateral episiotomy than midline episiotomy if repair was after placental delivery.

At spontaneous delivery, Carroli and Belizan (1999) in their systematic review reported the mean estimated blood loss to be less with a restrictive approach to episiotomy use than a routine approach (214ml vs 272ml, p=0.01, mean difference -58.0, 95%CI -107.57 to -8.43). This was based on the one trial in the review which reported blood loss as an

outcome (House et al. 1986), although a difference in blood loss of this magnitude is unlikely to be clinically significant. Harrison et al. (1984), House et al. (1986), Sleep et al. (1984), The Argentine Episiotomy Trial Collaborative Group (1993) and Eltorkey et al. (1994) reported a greater need for suturing with a routine approach to episiotomy use at spontaneous delivery which, from evidence already discussed, one could infer a greater risk of PPH. The relationship between PPH and episiotomy use at OVD has not however been tested in an RCT to date. The only study addressing blood loss from the cohort studies previously discussed regarding episiotomy use at OVD (chapter 1.13) was Youssef et al. (2005) who reported a higher rate of PPH where an episiotomy had been performed compared to no episiotomy although this did not achieve statistical significance (7.0% vs 4.1%, OR 1.56 95%CI 0.80 – 3.04).

1.15.4 Pain

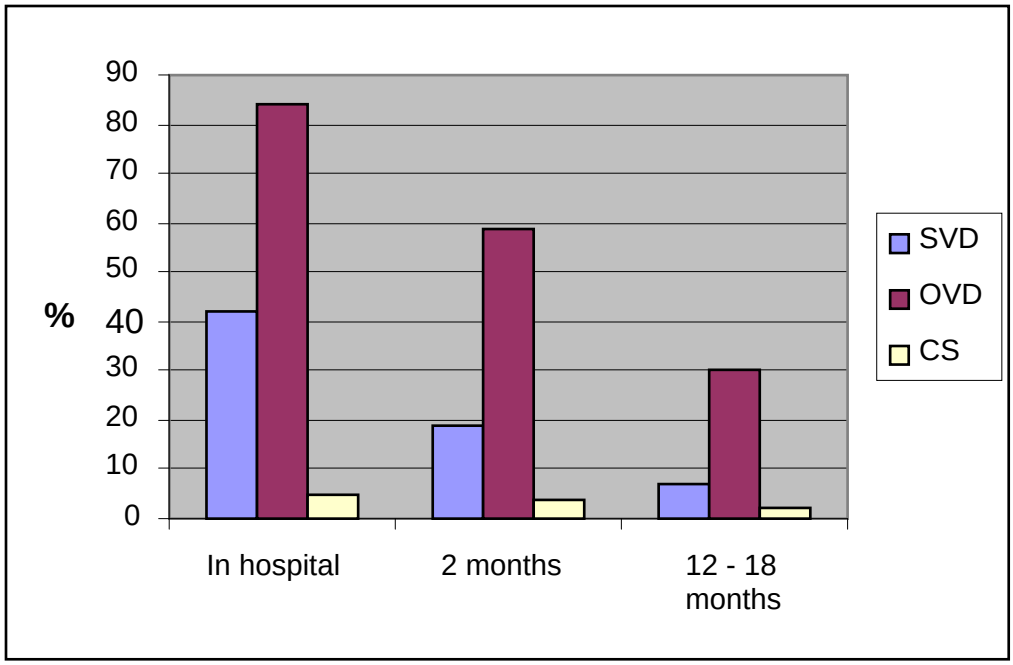
MacArthur and MacArthur (2004) reported immediate postpartum perineal pain to be common but an increasing incidence of perineal pain was associated with greater degrees of perineal trauma. In their study perineal pain was present on day one in 75% of women with an intact perineum, 95% with first /second degree tear, 97% with episiotomy and 100% with third/fourth degree tear. This pattern persisted to day seven, however, the incidence of pain reported had fallen to 38%, 60%, 71% and 91% respectively. By six weeks postpartum no statistically significant differences were found between the groups although no pain was reported by women with an intact perineum whereas 20% of women with a third/fourth degree tear were still experiencing pain. In addition to the observed differences in incidence the severity of pain reported increased with degree of trauma. Over one third of women sustaining an episiotomy used the word distressing or worse on the present pain intensity (PPI) scale of the McGill pain questionnaire on day one

as did 48% of women suffering an anal sphincter tear compared to 24% in the minimal trauma group or 13% where the perineum remained intact. Pain was reported to persist for longer also with increasing degrees of perineal trauma ranging from 1.9 weeks for women with an intact perineum, 2.4 weeks with minimal trauma, 2.6 weeks with episiotomy to 3.2 weeks for women with a third/fourth degree tear. Pain was found to be less reported in multiparous women compared to primiparae.

Support for these findings can be found in the study by Albers et al. (1999) in their analysis of data from the HOOP trial, an RCT comparing a "hands on" approach versus a "hands poised" approach to perineal management at vaginal delivery. They reported on perineal pain up to three months postpartum, and found that even women without perineal trauma experienced perineal pain at each time point (two days, ten days and three months postpartum) however in all cases, as expected, levels declined with time. More pain was experienced by primiparae versus multiparae, sutured versus unsutured trauma and with increasing degrees of trauma i.e. anal sphincter tears were associated with most postpartum pain.

Glazener (1999) found perineal pain to be significantly related to mode of delivery prior to hospital discharge, at two months and at 12-18 months postpartum. Rates diminished over time but a substantial proportion of women (30%) still complained of residual perineal pain up to 18 months after delivery (Figure 1.13).

Figure 1.13 Perineal pain by method of delivery to 18 months postpartum



Source Glazener 1999

A paper by Declerq et al. (2008) gives insight into women's postpartum experiences of pain by mode of delivery elicited from a representative national survey of women who gave birth during 2005 in the US. At spontaneous birth, women were significantly more likely to report perineal pain as a major problem in the immediate puerperium if episiotomy was performed rather than when no episiotomy was performed (32.9% vs 23.6%, p=0.03 in primiparae; 17.9% vs 5.1%, p<0.001 for multiparae). Perineal pain was commonly reported by mothers at OVD (by 77% primiparae and 52% multiparae). Mothers with both episiotomy and OVD were more likely to report perineal pain (77% with 43% describing it as severe) than those with either of these interventions alone (63% and 25% respectively). One third of primiparae reported pain which had interfered with their daily tasks (11% in a significant way). Pain persisting at six months postpartum was reported among 15% of primiparae delivered by OVD compared to 2% of primiparae

delivered by SVD. From these studies it would appear that OVD has significant implications in terms of pain which is exacerbated by the use of episiotomy.

A subjective assessment of post episiotomy pain was conducted by Reading et al. (1982) by interview within the first 24 hours after delivery and postal questionnaire follow-up at three months postpartum. A total of 101 women participated with follow-up data available on 69(68%). The majority (63%) reported pain from their episiotomy as "discomforting" at delivery with 10% rating it as "distressing" and 7% "horrible". At three months however 43% reported pain as "discomforting" whilst there was no change in the numbers reporting more significant pain. Almost all pain associated with their episiotomy was on sitting and a smaller proportion with pain on defecation although not with pain on micturition. They also found pain to be associated with the mode of delivery. More complex deliveries were associated with higher pain levels, a greater usage of postpartum analgesia and retrospective recall of episiotomy related pain through the puerperium.

From the evidence base of episiotomy use at vaginal birth (Carroli and Belizan 1999) there would appear to be no consensus on the effect of a restrictive approach to episiotomy use in terms of postpartum pain. Harrison et al. (1984) analysed perineal pain in the first four days postpartum among 77 primigravid women delivered spontaneously who had participated in their RCT of routine versus restrictive use of episiotomy at vaginal birth by the degree of trauma sustained. Forty participants were allocated to receive an episiotomy routinely, 37 were allocated to a restrictive use of episiotomy and had spontaneous tearing. Women who retained an intact perineum or sustained a first degree tear fared best as would be expected. Women who had an epidural anaesthesia and episiotomy fared worst with the highest degree of swelling and bruising. Analgesia requirements correlated well with the observed differences in pain measurements between groups and

over time. However, no significant differences were found between the two groups with regard to perineal pain or healing complications.

The RCT by Sleep et al. (1984) reported the severity and incidence of perineal pain, as assessed by mothers, was very similar for each study arm (liberal and restrictive use of episiotomy) at ten days and three months postpartum. Use of oral analgesia at ten days was reported in 3% of mothers in the restrictive group and 2% in the liberal group. At three months postpartum 12% of women in each group had sought medical advice due to perceived perineal problems. The findings in the study by Klein et al. (1992) were similar, with no significant differences in postpartum pain between groups.

One trial however, the Argentine Episiotomy Trial Collaborative Group (1993) reported that a selective approach to episiotomy use at vaginal delivery was associated with less perineal pain at hospital discharge than a routine approach [RR 0.72(95%CI 0.65 – 0.81)]. No results however were reported in any of the aforementioned trials of women who underwent OVD. This paucity of evidence requires to be addressed in any future RCT of episiotomy approach at OVD.

1.15.5 Infection and healing complications

The healing process commonly is divided into three main phases:

1. Inflammation consisting of a vascular and cellular response over the first three to five days
2. Proliferation consisting of granulation, wound contraction and epithelialisation which may last for up to three weeks
3. Maturation occurs in parallel with the previous two phases and consists of the laying down of collagen - in a random pattern initially becoming more organised

over time to produce increasing tensile strength, up to 80% of the original. This phase can last up to two years after the initial trauma

The majority of perineal trauma will heal very quickly by primary intention due to the increased vascularisation of the pelvic area during pregnancy and the immediate postpartum period however care must still be taken to optimise this process.

Infection is probably the main cause of an interruption in the normal healing process with the growth of bacteria thriving in the warm, moist environment of the perineum. Infection results in reduced collagen synthesis which causes the edges of the wound to soften and stitches to "cut out" of the tissue with subsequent wound dehiscence (Cuschieri et al. 2000).

Haematoma formation is another cause of wound breakdown with or without secondary infection and so care must be taken in suturing techniques. Healing in these instances is by secondary intention which is a more prolonged process involving granulation from the inside outwards. Delay in healing may allow the collagen layers laid down in the maturation phase to shorten. This leads to tissue deformity, excessive scar formation and a resultant poor cosmetic result.

The type of perineal trauma experienced may also have a bearing on the success of the healing process. Weber and Meyn (2002) in their review of US episiotomy use found, compared to women who sustained spontaneous perineal trauma, women with episiotomy were significantly more likely to have perineal wound breakdown (0.03% vs 0.005%, $p<0.001$) and a slightly longer hospital stay (mean 2.6 vs 2.3 days, $p>0.05$).

The Argentine Episiotomy Trial (1993) reported that a selective approach to episiotomy use at vaginal delivery was associated with less healing complications at hospital discharge than a routine approach, RR 0.69(95%CI 0.56 – 0.85) and dehiscence, RR 0.45(95%CI

0.30 – 0.75) but no differences were found in rates of infection or haematoma at seven days postpartum. Conversely, Harrison et al. (1984) found no cases of infection, wound breakdown or delayed healing in either arm of their study. These findings were however in women with any vaginal birth and do not address the relationship between episiotomy use and healing complications for women delivered by OVD. Further work is required to establish the implications if a restrictive approach to episiotomy were to be employed at OVD.

1.15.6 Dyspareunia

Dyspareunia may be defined as pain that occurs just before, during or after sexual intercourse that causes personal distress.

Dyspareunia is very often classified in the literature by severity and duration. Much attention has been paid to quantifying the incidence of dyspareunia in the short and long term after vaginal delivery. Clarkson et al. (2001) carried out a self reporting questionnaire survey to elicit the incidence of dyspareunia, urinary and faecal incontinence. Responses were received from 470 women (40% response rate) nine to 14 months postpartum, one hundred of whom had delivered by OVD (71 vacuum, 29 forceps). Dyspareunia at six weeks postpartum was reported by 74% of women following vacuum extraction and 77% of women following forceps delivery. Follow up at nine to 14 months reported dyspareunia persistent in 33% of cases post vacuum and 45% of cases post forceps. These rates were not significantly greater than those reported by women who had delivered spontaneously with an intact perineum (62% at six weeks and 37% at nine to 14 months respectively). Conversely Signorello et al. (2000) reported that relative to women with an intact perineum those with a second degree tear were 80% more likely and those with an anal sphincter tear 270% more likely to experience dyspareunia at three months postpartum.

At six months postpartum, OVD was significantly associated with dyspareunia (OR 4.4, 95%CI 2.7 – 7.0) and episiotomy was not found to confer any protection. Hicks et al. (2004) in a systematic review suggested an association between OVD and some degree of sexual dysfunction but concluded that continued research is necessary to identify modifiable risk factors related to method of delivery.

In addition, Clarkson et al. (2001) reported 49% of respondents to their questionnaire found dyspareunia had put a strain on their relationship with their partner, 30% had intercourse less frequently and in extreme cases their relationship had failed as a result. Despite this, relatively few had sought advice but those who did received little support and encountered a normalisation of these symptoms by carers– "normal after having a baby" or it would "go away by itself in time".

Hicks et al. (2004) conducted a systematic review of postpartum sexual functioning and method of delivery. They identified six studies which met their criteria comparing each delivery type separately, and presenting data on at least one relevant morbidity; perineal pain, dyspareunia, resumption of intercourse or self reported perception of sexual health (Figure 1.14).

Figure 1.14 Characteristics of included studies Hicks et al. (2004)

Author	Study Design and Data Sources	Sexual Function Measures
Barrett et al., England, 2000[7]	Retrospective cohort • Postal survey sent at 6 months postpartum asking retrospective questions about the year prior to pregnancy, first 3 months after birth, and currently (61% response rate) • Computerized database for age, social circumstances, medical history, obstetric details, infant birth weight, and infant gestational age	Detailed questions about resumption of intercourse or attempts including: • Problems experienced (prior to pregnancy and postpartum) • Sexual practices • Frequency of sexual intercourse • Satisfaction with sex life • Consultation for postnatal sexual problems
Brown and Lumley, Australia, 1998[22]	Cross-sectional • Postal survey at 6–7 months postpartum (62.5% response rate)	"Thinking about your own health and how you have been feeling since the birth, has any of the following been a problem for you?" A precoded list of health issues included painful perineum and sexual problems.
Glazener, Scotland, 1997[8]	Retrospective cohort • Postal survey following discharge from hospital, and at 8 weeks and 12–18 months postpartum (86%–90% response rate)	Questions about: • Perineal pain • Resumption of intercourse or attempts • Experience or anticipation of sexual problems
Lydon-Rochelle et al., United States, 2001[24]	Retrospective cohort • Postal survey sent at 5–7 weeks postpartum (59.4% response rate) • Postal survey linked to birth certificate and hospital discharge data	"How has delivery and mothering affected sexual activity in the last 2 weeks?"
Signorello et al., United States, 2001[23]	Retrospective cohort • Postal survey around 6 months postpartum (70.2% response rate) • Computerized database to identify perineal trauma	• Time to resuming sexual intercourse in weeks: <6, 6, 7–8, 9–12, >12 • Pain on sexual intercourse: yes, usually, sometimes, rarely, mild, moderate, severe, no
Thompson et al., Australia, 2002[5]	Prospective cohort • Postal survey at 4 days, 8, 16, and 24 weeks postpartum (92% response rate)	"Thinking about your health and how you have been feeling over the past 8 weeks, have any of the following been a problem for you?" A list of 12 common health problems followed, including sexual problems and sore perineum.

The largest study was Brown and Lumley (1998) who found perineal pain and sexual morbidity to be significantly more likely at OVD than SVD after adjustment for duration of labour, degree of perineal trauma and birth weight (OR 4.69, 95%CI 3.2 – 6.8 and OR 2.06, 95%CI 1.4 – 3.0 respectively). A limitation of this study is that no adjustment was made for parity so it is not possible to rule out contributory factors in a previous delivery. Barrett et al. (2000) investigated a total cohort of primiparous women delivering in their hospital over a six month period to ascertain the incidence of sexual morbidities and risk factors associated with them. High levels of sexual morbidity were identified - 62% of women experiencing dyspareunia at three months and 31% at six months (pre-pregnancy levels were reported as 12%). Risk factors identified included mode of delivery with dyspareunia most strongly associated with OVD at three months postpartum (OR 2.17, 95%CI 1.23 – 3.81) after correcting for degree of perineal trauma, breast feeding and

pre-pregnancy dyspareunia. They also identified a lack of support for women experiencing problems and a reluctance on the part of women to seek help. Signorello et al. (2001) similarly found OVD to be significantly associated with dyspareunia at six months postpartum (OR 2.5, 95%CI 1.3 – 4.8) compared with spontaneous delivery after correction for previously identified risk factors.

Glazener (1999) found perineal pain to be significantly related to dyspareunia indicating a causal relationship - 51% women with perineal pain experienced dyspareunia vs 22% of women with no pain at two months postpartum, $p<0.001$ and 52% vs 16%, respectively at 12-18 months, $p<0.001$. This study included primiparae and multiparae and adjusted for breastfeeding and depression only.

Lydon-Rochelle et al. (2001) found resumption of sexual activity to be significantly longer in women delivered by OVD and delivery to be significantly more likely to have adversely affected sexual functioning compared to women who delivered spontaneously.

Sartore et al. (2004) performed a comparison of perineal strength and dysfunction in women receiving an episiotomy compared to those with an intact perineum or first/second degree laceration at three months after first vaginal delivery. Their findings supported Carroli's conclusion that episiotomy is not protective of urinary or faecal morbidity however higher rates of dyspareunia (7.9% vs 3.4%, $p=0.026$) and perineal pain (6.7% vs 2.3%, $p=0.014$) were found in the episiotomy group. Episiotomy was associated with greater perineal weakness on digital testing and vaginal manometry which may have implications for genital prolapse in the longer term.

Buhling et al. (2006) compared morbidity in 655 women by four groupings – SVD without perineal injury, delivery by CS, SVD with episiotomy or perineal laceration and OVD combined with routine episiotomy. No significant differences were found in the time to resumption of sexual activity in the puerperium between groups. There was an association

however between mode of delivery and pain on first sexual experience postpartum. Pain was significantly more likely in women delivered by OVD (52.0%) and SVD with episiotomy/laceration (53.6%) than women who delivered spontaneously without perineal trauma (36.4%) or by CS (40.2%) (p=0.007). They also explored the duration of sexual morbidity and again longer duration was found to be significantly more associated with OVD and SVD with episiotomy/laceration than SVD without perineal trauma or CS (p=0.049). Sexual morbidity lasting longer than six months was experienced by 9% of OVD and 7.6% of SVD with episiotomy/laceration compared to 2.6% of SVD without perineal trauma and no cases in women delivered by CS. A limitation of this study was it's low response rate (40.6%) however higher response rates were seen in the OVD and episiotomy groups which may be indicative of the increased morbidity burden in these groups with women not experiencing problems being less likely to respond as they might perceive the questionnaire as being less relevant to their circumstances. These findings were supported by Baksu et al. (2007) who also examined the effect of mode of delivery on sexual functioning in primiparae. All measures of sexual morbidity (desire, arousal, lubrication, orgasm, satisfaction and pain) were found to be significantly more likely after a vaginal delivery with mediolateral episiotomy compared to pre-pregnancy levels, global score ($p< 0.001$) with no such association found at CS.

The comparison groups in these studies and others (Andrews et al. 2006; Ejegård et al. 2008) either did not differentiate between episiotomy and spontaneous tearing or compared episiotomy with an intact perineum however Signorello (2001) analysed data from their retrospective cohort study by type of perineal trauma and reported episiotomy conferred the same profile of sexual outcomes as spontaneous tears. Dyspareunia at three months postpartum was more likely following a second degree tear (OR 1.8, 95%CI 1.2 – 2.8) and third or fourth degree tear (OR 2.7, 95%CI 1.7 – 7.7) compared to an intact

perineum. OVD was also found to be significantly more associated with dyspareunia at six months postpartum (OR 2.5, 95%CI 1.3 – 4.8).

Sleep et al. (1984) reported that 33% of primiparae randomised to a restrictive use of episiotomy had resumed intercourse by four weeks after delivery as compared to 22% of primiparae allocated to a liberal use ($p<0.01$). Nearly all women (90%) had resumed sexual intercourse within three months of delivery and the proportions were the same in both trial arms. Of these women 52% in the restrictive group and 51% in the liberal group had experienced dyspareunia at some time with 22% and 18% respectively still reporting problems at three months postpartum. Women who had had severe trauma when contacted 21 months after delivery reported it had taken up to 18 months for intercourse to become completely comfortable. A follow up to this study three years post delivery Sleep and Grant (1987) found no differences between the two groups in terms of dyspareunia. Similarly Bahl et al. (2005) compared pelvic floor symptoms in 283 women three years after delivery by OVD or CS in the second stage of labour and found no significant differences in terms of sexual symptoms.

Sexual morbidities may have serious long term implications for the wellbeing, not only of women, but their relationships and children's welfare. Any modification of interventions which might impact on the incidence of perineal pain or trauma warrants investigation in an RCT.

1.15.7 Psychological morbidity

There is some evidence that childbirth can, for a proportion of women, be a traumatic experience which has an ongoing psychological impact on their lives in both the short and longer term in terms of morbidity and plans for a future pregnancy.

"Birth trauma" refers to a fundamentally negative birth experience that may be either physical or psychological in origin.....or from a combination of these (Littlewood and McHugh 1997). Altered body image, a perceived physical trauma and feelings of being out of control or ill informed about a procedure may all have a role to play. Birth trauma is a complex concept involving the understanding of a particular intervention for a specific individual.

No studies were identified which directly investigated the relationship between episiotomy use at OVD and psychological morbidity however there is some evidence that OVD and perineal trauma are associated with some degree of psychological morbidity.

Several studies have explored the impact of suboptimal outcomes of pregnancy on women's psychological wellbeing and the effect of dissatisfaction with the care received during pregnancy and the puerperium. Post traumatic stress disorder (PTSD) is a severe anxiety disorder that can develop after exposure to any event that results in psychological trauma (American Psychiatric Association, 1994). Adewuya et al. (2006) conducted a cross sectional survey to assess levels of PTSD in a cohort of Nigerian women. They found OVD (OR 7.94, 95%CI 3.91 – 16.15) and poor maternal experience of control during childbirth (OR 5.05, 95%CI 2.69 – 9.48) to be independently associated with PTSD. Previous work by the same author (Adewuya et al. 2005) explored risk factors for depressive illness postpartum in a Nigerian community. In that study 876 women were screened six weeks postpartum using the Edinburgh postnatal depression scale (EPDS). Depression was diagnosed in 128(14.6%) of participants and OVD was identified as a predictor of postnatal depression (OR 3.32, 95%CI 1.79 – 6.16).

Qualitative work by Salmon (1999) sought to recognise the psychological impact of perineal trauma by listening to women describe a spectrum of negative feelings towards perineal trauma and morbidities in the first postpartum month. Women had experienced a

"normalisation" of their perineal pain and their anxiety about the physical appearance of the traumatised perineum. They felt health care professionals dismissed or redefined their feelings as normal. Emotions such as anxiety and fear, some of which persisted up to five years after the traumatic delivery, had prevented timely recovery from the experience especially in terms of recommencing sexual relationships and considering future pregnancy.

Herron-Marx et al. (2007) conducted semi structured interviews with 20 postpartum women exploring their views of enduring postnatal perineal and pelvic floor morbidities. Women with serious sexual morbidities commonly reported feelings of embarrassment and isolation with an inability to share their condition with a partner and a resultant deterioration in the relationship.

Murphy et al. (2003) explored women's views on the impact of OVD in qualitative interviews with 27 women. Some women described the uncontrollable nature of their delivery and the feeling of being unprepared for such a delivery and feelings of failure that little of their hopes regarding delivery i.e. their Birth plan had actually been achieved.

'…birth plan, my birth nightmare, after months of preparation it just went out the window'

Bahl et al. (2004) explored women views on subsequent pregnancy three years after an operative delivery whether vaginal or caesarean. They reported 32% of women wished to avoid future pregnancy with fear of childbirth being a frequently cited reason (51% after OVD, 42% after CS).

Brown and Lumley (1998) described the prevalence of maternal physical and psychological morbidities six months postpartum via a state-wide postal survey in Victoria, Australia of all women with a live infant who delivered during a two week period in 1993. Compared to SVD they found women delivered by OVD were more likely to report perineal pain (OR 4.69, 95%CI 3.2 – 6.8), sexual problems (OR 2.06, 95%CI 1.4 – 3.0), and UI (OR 1.81,

95%CI 1.1 – 2.9). In addition women who had an episiotomy were found to be significantly more likely than women with a tear requiring suturing to report perineal pain (44.6% vs 29.8%, OR 1.90, 95%CI 1.4 – 2.6) and sexual problems (34.8% vs 26.6%, OR 1.47, 95%CI 1.1 – 2.1). They identified 16.9% of their cohort as depressed using the EPDS although no analysis was made of the relationship between depression and degree of perineal trauma.

Rouhe et al. (2008) using the Wijma Delivery Expectancy/Experience questionnaire (W-DEQ) in their survey of 1400 women attending outpatient maternity clinics in Helsinki, Finland supported these findings as they demonstrated that women with a previous vacuum extraction had higher fear scores of future childbirth than those without (W-DEQ 70.6 ± 19.7 vs 64.8± 22.0, $p<0.05$).

In contrast Neilsen Forman et al. (2000) found no association between delivery complications and postpartum depression in their large Danish prospective questionnaire study of women four months after delivery. They found 12.8% of the depressed group were delivered by OVD vs 13.0% of the non-depressed group (OR1.0, 95%CI 0.7 – 1.4).

These data provide us with a snapshot of the psychological impact that OVD can have and the emotions generated are those described in Littlewood and McHugh (1997) which may contribute to feelings of depression or post traumatic stress. This is an important but perhaps undervalued aspect of postpartum morbidity which should be explored with regard to episiotomy use at OVD.

Reading et al. (1982) showed the pain rating of episiotomy correlated negatively with mood (r=-0.44 at delivery and -0.28 at three month follow-up). Pain then may contribute to disturbance of postpartum mood and likewise mood may impact on the level of perceived pain as dysphoria amplifies pain sensation. Pain may also affect the mother's attitudes and behaviour towards her baby. The perception of postpartum pain may be

mitigated by the joy of the baby while conversely the pain experienced may detract from the experience of motherhood. This aspect of postpartum care warrants investigation in an RCT of episiotomy use at OVD.

1.16 Neonatal Morbidities Associated With Operative Vaginal Delivery

Neonatal injury may include bruising, lacerations, cephalhaematoma, retinal haemorrhage or brachial plexus injury (BPI). Most superficial neonatal trauma resolves within days to weeks but can generate considerable parental anxiety. Other morbidities can persist with long-term consequences for the child.

The risk of birth trauma to infants delivered at term is low (two per cent) but is more likely as a sequelae to OVD (13%) (Baskett et al. 2007). In this study composite measures of fetal trauma were categorised as major (depressed skull fracture, intracranial haemorrhage or BPI) or minor (linear skull fracture, other fractures, facial palsy or cephalhaematoma). Trauma rates were highest following failed OVD (failed vacuum, 0.8% major and 9.7% minor trauma; failed forceps, 0.8% major and 4.9% minor trauma respectively) but were also greater with one instrument usage at OVD (vacuum, 0.4% major and 6.7% minor trauma and forceps, 0.5% major and 5.3% minor trauma respectively) compared to spontaneous delivery. These findings support the recommendation of the RCOG (Green top guideline No. 26) that sequential use of instruments should be avoided if at all possible.

Benedetto et al. (2007) also observed forceps assisted and vacuum assisted deliveries to be most associated with neonatal trauma when compared with SVD (OR 1.4, 95%CI 0.4 – 5.3 and OR 6.7, 95%CI 2.6 – 17.1 respectively) and OVD when compared with CS in labour (OR 4.2, 95%CI 2.4 – 7.4). A significantly higher incidence of neonatal trauma was

identified in vacuum assisted versus forceps assisted deliveries (OR 3.8, 95%CI 1.3 – 17.8) which agrees with other studies (Johanson and Menon 1999; Baskett et al. 2007).

A review of the literature was carried out to assess the rates of individual neonatal morbidities associated with OVD and to establish what is known about the relationship between episiotomy use and these sequelae.

1.16.1 Bruising/lacerations

Bruising and minor abrasions to the scalp and facial skin are very common following OVD and whilst causing parental upset are usually mild and quickly resolve. In most cases localised treatment, if any, is sufficient however in more severe cases, where the infant shows signs of experiencing pain, analgesia may be administered. Excessive bruising can have a bearing on the development of neonatal jaundice which if at a significant level will require treatment and may prolong hospitalisation.

Several studies have reported on the incidence of minor head trauma e.g. bruising, blisters, abrasions and lacerations.

Johanson and Menon (1999) in their Cochrane review of six trials exploring vacuum extraction versus forceps for assisted vaginal delivery found scalp/ facial injuries to be no more associated with forceps delivery than vacuum extraction (17.5% vs 16.6%, OR 0.89, 95%CI 0.70 – 1.13).

Baskett et al. (2008) in their prospective cohort study of 1000 vacuum assisted deliveries reported minor trauma in 13.4% of infants of primiparous women and 6.0% of infants to multiparous women. They reported all traumas had resolved within a few days without complication.

Johnson et al. (2004) in their retrospective cohort study of neonatal effects of OVD identified more instrument marks and bruising in neonates delivered by forceps compared

to vacuum (36.5% vs 10.7%, OR 4.63, 95%CI 2.90 – 7.41). They found a greater episiotomy rate in their cohort at forceps delivery compared to vacuum extraction (90.5% vs 81.8%, p=0.01) however on multivariable logistic regression episiotomy use was not found to be associated with instrument marks and bruising at forceps delivery (OR 0.96, 95%CI 0.47 – 1.93).

Teng and Sayre (1997) conducted a prospective cohort study of 134 vacuum extraction-assisted deliveries over a one year period to identify variables that increased the chance of neonatal scalp injury during vacuum extraction. They found 28(21%) neonates to have scalp trauma – 17(12%) with superficial lacerations, 6(4%) with severe caput, and 12(9%) with cephalhaematoma. Logistic regression analysis showed duration of vacuum application to be the best predictor of scalp injury. Injury was more likely where application exceeded ten minutes. These findings have important implications in a trial comparing approaches to episiotomy use at OVD as modification in the delivery technique may impact on the length of instrument application and so warrant further examination in any proposed study.

1.16.2 Cephalhaematoma

Cephalhaematoma is a collection of blood between the periosteum and skull bones that doesn't cross the suture lines. It is caused by trauma, commonly during OVD especially vacuum extraction and may develop up to several hours after delivery. In the majority of cases no treatment is required although occasionally admission to the neonatal unit is justified. It will normally be absorbed within a few weeks with no persisting morbidity. A short term implication of cephalhaematoma may be hyperbilirubinaemia necessitating treatment and prolongation of the hospital stay if sufficiently significant.

Cephalhaematoma has been shown to be significantly more associated with vacuum extraction than forceps delivery. Johanson and Menon (1999) reporting on six trials found an incidence of 9.9% at vacuum vs 4.1% at forceps assisted deliveries (OR 2.38 95%CI 1.68 – 3.37).

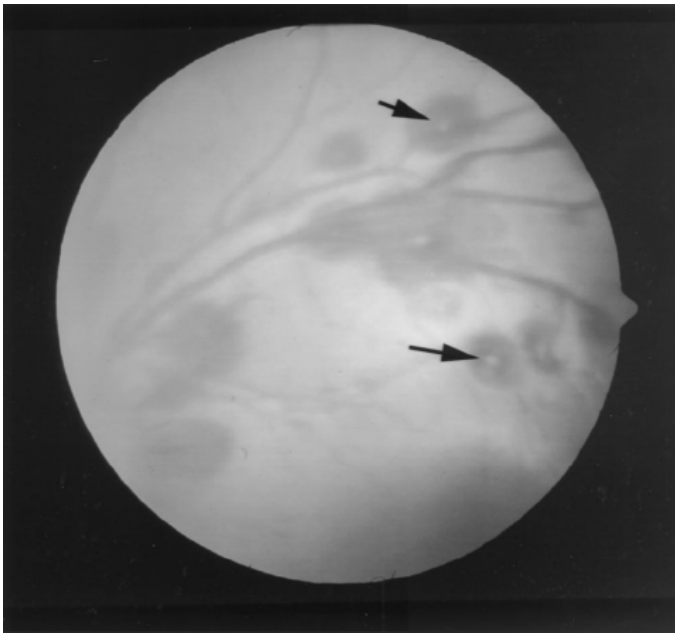
Only one trial could be found which investigated the relationship between episiotomy use and cephalhaematoma. Johnson et al. (2004) in their retrospective cohort study of neonatal effects of OVD identified a significantly lower risk of cephalhaematoma in neonates delivered by forceps compared to vacuum [12.5% vs 20.5%, OR 0.56(95%CI 0.33 – 0.94)] similar to the findings of Johanson and Menon (1999). On multivariable logistic regression episiotomy use was not found to be preventative for cephalhaematoma (OR 1.53, 95%CI 0.71 – 3.30).

1.16.3 Retinal haemorrhage

Retinal haemorrhage in the neonate (Figure 1.15) is most commonly intraretinal and is classified by;

- type - splinter, flame, lake and blob haemorrhages
- area of haemorrhage - Zone I, II and III
- severity - grade I (one or two haemorrhages), grade II (three to ten haemorrhages) and grade III (more than ten haemorrhages).

Figure 1.15 Fundus photograph of a Zones I and II, Grade III retinal haemorrhage in the first day postpartum



The majority of investigators attribute retinal haemorrhage to obstetric trauma. Sezen (1971) found retinal haemorrhage to be more commonly associated with vacuum extraction (40.3%) and forceps assisted deliveries (33.3%) than SVD (14.2%) or CS (0.8%). They also identified primiparity as a risk factor (20.0% primiparae vs 11.3% multiparae, $p<0.001$). Hughes et al. (2006) performed a prospective study screening 53 neonates for retinal haemorrhage using indirect ophthalmoscopy. They identified 18 cases of retinal haemorrhage. Analysis of incidence by mode of delivery revealed a strong association between retinal haemorrhage and vacuum delivery (vacuum extraction 77.8%; forceps delivery 30.3%; SVD 30.4% and CS 8.3%). All haemorrhages were intraretinal and had resolved by 16 days in all but two cases which persisted for 31 and 58 days. Both of the most persistent haemorrhages were delivered by vacuum extraction. Emerson et al.

(2001) investigated the relationship between episiotomy use at and this morbidity. They found no association between episiotomy use and the incidence of retinal haemorrhage (33.3% with episiotomy vs 33.6% without episiotomy) at vaginal delivery.

1.16.4 Intracranial haemorrhage

Subdural haemorrhage is the most common type of intracranial bleed following birth trauma. It results from tears in the dura of the falx or tentorium cerebelli. These tears are associated with primiparity, macrosomia or difficult delivery - all situations which may exert greater pressures on intracranial vessels. The presenting signs may include seizures, hypotonia, a poor Moro reflex, a rapidly enlarging head or extensive retinal haemorrhages. Surgical intervention may be necessary and prognosis is guarded in this type of haemorrhage.

Subdural haemorrhage was thought to be uncommon in term infants. There is evidence to suggest that this morbidity can be found in about 7% of SVD or OVD however sequential use of instruments at OVD is more commonly associated with subdural haemorrhage. Whitby et al. (2004) performed a study on asymptomatic term infants to establish the frequency of subdural haemorrhage by mode of delivery. Of 111 babies scanned nine were found to have a subdural haemorrhage (8.1%). Sequential instrument use was significantly more associated with subdural haemorrhage than SVD [27.8% vs 6.1%; OR 5.9(95%CI 1.24 – 1.28)] whereas no differences were found between SVD and vacuum delivery [6.1% vs 7.7%; OR1.28 (95%CI0.12 – 13.4)]. No cases were identified following forceps delivery. In all cases that subdural haemorrhage was identified the baby was assessed clinically but no treatment was required. All haemorrhages had resolved when rescanned at four weeks of age.

Subarachnoid haemorrhage is less commonly associated with birth trauma and also arises from torn venous structures. Affected neonates may present with seizures, apnoea, lethargy and abnormal neurological findings. Conservative or supportive management is normally sufficient and prognosis following this type of haemorrhage is usually good.

Intraventricular haemorrhage is the least common type of intracranial haemorrhage but the most serious in terms of mortality and morbidity. It is most often associated with prematurity, the risk being inversely related to gestational age and birth weight (Linder et al. 2003). Hypoxic ischaemia often precedes this type of haemorrhage as it causes damage to the capillary epithelium, impairs cerebral vascular blood flow and can increase cerebral blood flow and venous pressure all of which make haemorrhage more likely. Infants with a small intraventricular bleed most often do well but if the bleed is large the prognosis is poor, especially if the haemorrhage extends into the parenchyma.

Symptomatic intracranial haemorrhage is then a rare event reported equally with the use of both forceps and vacuum. Simonson et al. (2007) reported an incidence of 0.87% after vacuum extraction; Towner et al. (1999) reported an incidence of 0.12% after vacuum extraction and 0.15% after forceps delivery (OR 1.2, 95%CI 0.7 – 2.2) and Demissie et al. (2004) also found the risk of intracranial haemorrhage to be comparable between forceps and vacuum (OR 0.94, 95%CI 0.79 – 1.12). Towner et al. (1999) identified a greater risk of intracranial haemorrhage where sequential instruments were used [OR 2.7(95%CI 1.2 – 6.3)], evidence which was supported by Gardella et al. (2001) who reported the relative risk of using both instruments approached the sum of the relative risk of using either instrument alone compared to SVD.

Although rare, its consequences may be serious. Over the period 1994 – 1998 the US Food and Drug Administration (FDA) had received reports of 12 deaths and nine serious injuries among newborns delivered by vacuum extraction, an average of five events per

year which contrasted with fewer than one event per year in the preceding 11 years there This increase in reported morbidity was partly attributed to an increase in usage, from 3.5 percent of all deliveries to 5.9 percent, however the FDA was sufficiently concerned to issue specific recommendations in an attempt to minimise such trauma e.g. applying a steady traction rather than a rocking motion, avoiding the use of sequential instruments (US Food and Drug Administration 1998).

There is no current evidence to support the relationship between episiotomy use at OVD and this morbidity.

1.16.5 Shoulder dystocia

Shoulder dystocia occurs when the shoulder (more commonly the anterior shoulder) impacts against the maternal symphysis or sacral promontory following delivery of the vertex. It is not then possible to complete delivery of the infant with the normal degree of downwards traction and additional manoeuvres are required to expedite the delivery. Although clearly this scenario is both a maternal and neonatal emergency for the purposes of this thesis it is presented as the latter in terms of addressing its possible sequelae in the neonate.

The implications for both the mother and neonate can be severe if delivery is delayed (Gherman et al. 1998). Maternal complications may include soft tissue injuries, anal sphincter damage, PPH, uterine rupture and symphyseal separation. Neonatal complications (described in greater detail later in this chapter) may include BPI, clavicle/ humeral fracture, fetal acidosis leading to hypoxic brain injury and even death. Umbilical artery pH levels in this scenario drop by 0.4 per minute.

The incidence of this complication of labour is low at 0.6% (Gherman et al. 1998; Al Hadi et al. 2001) but it's consequences are sufficiently grave that evaluation of any modification

to a delivery intervention should assess the impact on shoulder dystocia as part of a study as planned in this thesis.

A routine approach to episiotomy has historically been advocated to prevent severe shoulder dystocia. Al Hadi et al. (2001) found a significantly higher episiotomy rate in cases with shoulder dystocia compared to matched controls without (57.4% vs 33.3%, $p<0.0001$). In Bofill's study (Bofill et al. 1997) however there was no significant association between the use of episiotomy and delivery complicated by shoulder dystocia ($p=0.62$).

The traditional role of episiotomy has been challenged by the Managing Obstetric Emergencies and Trauma Group who suggest a restrictive approach to episiotomy use may be more appropriate i.e. only to be employed if considered necessary to facilitate manoeuvres required to execute delivery. This approach is supported by evidence from Gurewitsch et al. (2004) who compared maternal and neonatal outcomes at deliveries complicated by severe shoulder dystocia managed by episiotomy versus fetal manoeuvres. They concluded that if delivery can be achieved without the use of episiotomy then severe perineal trauma can be averted. Anal sphincter tears were found to be significantly more common when episiotomy was employed with or without the use of fetal manipulation (62.5%, 68.2% respectively) compared to when episiotomy use was avoided (fetal manipulation alone, 10.7%, $p<0.0001$). In addition, there was a similar incidence of BPI between births employing episiotomy alone and episiotomy in conjunction with fetal manipulation (59.1% and 58.3% respectively, $p=0.95$) however if episiotomy use was avoided and only fetal manipulation was employed to expedite delivery significantly fewer births were complicated by BPI (35.1%, $p=0.05$). In addition Gherman et al. (1996) reported the rate of anal sphincter trauma to be increased in cases with shoulder dystocia, citing a fourth degree tear rate of 3.8% and Al Hadi et al. (2001) found the rate of third

degree tears was significantly higher in the group of women that had shoulder dystocia compared to matched controls despite the higher episiotomy rate associated with this complication.

No studies from the evidence base of episiotomy use at SVD reported on the relationship between episiotomy use and shoulder dystocia. From the retrospective cohort studies regarding episiotomy use at OVD described previously (Combs et al. 1990; Helwig et al. 1993; Robinson et al. 1999; Johnson et al. 2004; Kudish et al. 2006; Bodner-Adler et al. 2003; Youssef et al. 2005; Hudelist et al. 2005; de Leeuw et al. 2008) there would appear to be no relationship between shoulder dystocia and episiotomy use. In most cases shoulder dystocia was not noted as an outcome measure, however, Helwig et al. (1993) found no association between episiotomy use and shoulder dystocia (episiotomy was employed in 33.3% of cases with shoulder dystocia vs 41.8% of cases without shoulder dystocia, p=0.37); Robinson et al. (1999) reported no differences in the likelihood of anal sphincter tears occurring between cases of shoulder dystocia delivered by forceps vs vacuum (OR 0.7, 95% CI 0.2 – 2.0) and Youssef et al. (2005) found no association between shoulder dystocia and episiotomy (6.9% with episiotomy vs 4.6% without episiotomy, adjusted OR 1.43, 95%CI 0.74 – 2.76).

1.16.6 Brachial plexus injury

Damage to the brachial plexus, the main group of nerves serving the upper arm, is caused by lateral flexion of the neck during delivery which may be secondary to excessive traction in the case of a difficult delivery. Brachial plexus injury affects the upper arm alone whereas Erb's palsy also affects the lower arm and hand. Damage is done to the nerves at the level of the 5^{th} and 6^{th} cervical spine causing paralysis of the abductors and flexors of the upper arm. There is an absence of the Moro or startle reflex on the affected side. In

Erb's palsy the arm is typically said to take the position of "waiter's tip" in which the hand is rotated internally (Figure 1.16).

Figure 1.16 Erb's palsy and waiter's tip position of the affected arm

The extent of damage may range from neuropraxia which resolves spontaneously without treatment, other than physiotherapy to maintain a full range of movement until healing occurs, to rupture or avulsion of the nerves. Residual paralysis can vary from mild in the case of neuroma formation due to scar formation at the damage site to severe, long term damage which has a poor prognosis and may require surgical intervention at a later stage to try to compensate for the residual deficit. If long term damage is sustained the physical development of the affected arm may be impaired along with its motor, sensory and circulatory function. Surgical treatment can include nerve grafting, tendon transfer and release of contractures.

No studies could be found in the literature investigating if there is a relationship between BPI and episiotomy use at OVD.

1.16.7 Fracture

Depression fracture of the skull is an uncommon occurrence caused by excessive pressure being applied through the tip of the forceps blade in a difficult delivery. No treatment is required unless cerebral irritation is evident in which case surgical intervention may be indicated.

Fracture of the clavicle and humerus are also possible as a result of a forceful delivery. Fracture may be indicated by the absence of the Moro reflex in the affected limb. Callus formation is rapid in the healthy neonate and so splinting is not generally required.

Baskett et al. (2007) reported fractures occurring following 0.21% of OVD. Depressed skull fracture (0.003%) and linear skull fracture (0.006%) accounted for less than 0.01% of neonatal morbidities.

No studies could be found in the literature investigating if there is a relationship between the incidence of fracture and episiotomy use at OVD.

1.16.8 Feeding

Mothers and babies share a natural instinct to be close after birth. Holding your baby with skin-to-skin contact within the first hour of life has many benefits, for example, it makes breastfeeding easier, enhances bonding, and also helps the neonate regulate temperature and blood glucose levels and cry less (Porter 2004). Mizuno et al. (2004) reported that a brief period of skin to skin contact immediately after birth and suckling at the breast enhanced neonates' recognition of their mothers' milk odour with a lasting effect on the success of breast feeding. There is some evidence that the release of oxytocin that accompanies breast feeding, in addition to benefits in maintaining a well contracted uterus and minimising blood loss may have a psychological role to play in the control of maternal responsiveness in humans as in other animals with implications for bonding and prolonged

breast feeding. Interruption of this important time in the mother-infant relationship may then have significant implications for the health of both the mother and her infant and should be avoided if at all possible. These findings have particular relevance when considering the approach to episiotomy use at OVD. Karaçam and Eroğlu (2003) in their prospective cohort study described previously reported that the mean time from delivery to maternal rest and time taken to bond was significantly longer in mothers who had an episiotomy performed than those with no episiotomy at SVD. Their investigation of time to bonding between the mother and infant found that 26% of mothers delivered without episiotomy had contact with their baby within 30 minutes of delivery compared to only two per cent of women delivered with episiotomy ($p<0.001$), (62% vs 60% within an hour and 12% vs 38% greater than an hour respectively). This has important implications for the health of the mother and her infant from a healing and establishment of breast feeding perspective and so the impact of a restrictive approach to episiotomy use at OVD should be investigated in this context.

1.17 Conclusions of the literature search

Operative vaginal delivery and episiotomy are both interventions which are in common practice in the UK and worldwide to assist the delivery of a healthy infant. Despite a rising use of CS in the western world the incidence of OVD has remained fairly constant although instrument preference varies geographically and has changed over time. Both episiotomy and OVD are more likely to occur at first delivery, with a big baby and prolonged labour and are predominantly associated with each other.

The routine use of episiotomy at SVD has been shown to be associated with an increased risk of anal sphincter tearing whereas conflicting evidence is available regarding the relationship between episiotomy use and OVD and anal sphincter tearing. From this

systematic search of the literature a paucity of evidence exists to either support or refute a routine approach to episiotomy use at OVD as has historically been the norm and a restrictive use has crept in to practice. This lack of evidence on which practitioners can base their decision making has led to a variation in the usage of episiotomy at OVD at a national, institutional and individual level. As a result this aspect of OVD has been identified as requiring further research to better inform clinicians and allow them to make decisions about episiotomy use at OVD which are evidence based.

The series of studies which form the basis of this thesis have been designed to address issues relating to episiotomy use at OVD and its impact on maternal and neonatal complications.

1.18 Aims and Objectives

The objective of the series of studies reported in this thesis is to assess the effects of routine use of episiotomy compared with restrictive use of episiotomy at OVD. Specifically this thesis will attempt to assess if the approach to episiotomy use has any effect on the incidence or severity of the maternal and neonatal morbidities discussed in this chapter particularly anal sphincter tearing.

The design of this study follows the recommendations of the Medical Research Council (MRC) framework for design and evaluation of complex interventions (figure 1.17) which recommends that trials should be underpinned by formative work that informs and moulds its design.

Figure 1.17 MRC framework for design and evaluation of complex interventions

Stepwise approach (on paper):

Phase 0—Preclinical or theoretical (why should this intervention work?)

Phase 1—Modelling (how does it work?)

Phase 2—Exploratory or pilot trial (optimising trial measures)

Phase 3—Definitive RCT

Phase 4—Implementation

Parallel approach (in practice):

Combine phases 0-II into one larger activity to develop understanding of the problem, the intervention, and the evaluation

The aims of this series of studies are as follows:

- to explore the current perceptions and practice of obstetricians in the UK and Ireland with regard to episiotomy use and OVD
- to establish the need for assessment of differing approaches to episiotomy use at OVD and the acceptability to clinicians of a study comparing two approaches to episiotomy use at OVD
- to assess the acceptability and feasibility of conducting an RCT of restrictive versus routine use of episiotomy at OVD
- to design and conduct a pilot RCT of restrictive versus routine use of episiotomy at OVD
- to determine recommendations for future research

Chapter 2 - A National Survey Of Clinical Practice At Operative Vaginal Delivery And The Use Of Episiotomy

2.1 Introduction

As part of the formative work in preparation for the proposed pilot RCT of a routine versus restrictive use of episiotomy at OVD, I sought to explore what *a priori* views were held by obstetricians in the UK regarding the relationship between episiotomy use and OVD, to investigate current practice in this area of medical intervention in the birth process and gauge willingness to recruit to and participate in the proposed RCT.

2.2 Methods

2.2.1 Choice of survey method

A questionnaire survey was proposed as this methodology is "an objective means of collecting information about people's knowledge, beliefs, attitudes and behaviour" (Boynton and Greenhalgh 2004).

A postal questionnaire survey is a cost effective method of gathering information. It is ideal for large sample sizes or when the sample comes from a wide geographic area. Because there is no interviewer, there is no possibility of interviewer bias. Recognised limitations of the method are that questionnaire design is key to the quality of information received, response rates are often poor and there is no opportunity to supplement the questionnaire with observational data (Bowling 2002). Despite these limitations a postal survey was considered the most effective method to gather information required to present an overview of current practice.

As no previous survey of obstetricians to investigate *a priori* views or current practice regarding episiotomy use and OVD was identified in the literature the development of a new instrument was necessary.

A well designed survey will increase response rates and optimise the quality of information gleaned (McColl et al. 2001). With this in mind, attention was paid to the physical layout of the questionnaire; keeping questions short and concise and looking for information on only one dimension whilst trying to accommodate all possible answers (Appendix 4). Clear instructions on how to complete the questionnaire were provided in bold font with key items in italics. Questions regarded as being more relevant and interesting to the participants were placed first and personal questions were kept to last. The questionnaire was anonymised to increase the likelihood of producing honest responses. Quantifying adjectives (e.g., always, frequently, rarely) were used in questions and when considering the results it is important to bear in mind that these adjectives may mean different things to different people.

Edwards et al. (2002) published a systematic review of 292 RCTs investigating 75 strategies for influencing response to postal questionnaires. Their findings informed the methodology adopted for this survey within the confines of affordability. Incentives, recorded delivery or prior contact were not considered possible although identified as increasing response rates. Brown envelopes were used as opposed to white, a stamped return envelope versus business reply or franked envelope and postal follow up to initial non respondents was performed enclosing a replacement questionnaire. An explanation for nonparticipation was requested. The origin of the questionnaire being a university department and under the supervision of a well respected expert in the area of interest would be likely to be an advantage.

One disadvantage of questionnaires is the inability to probe responses as they are structured instruments. Questionnaires allow little flexibility to the respondent with respect to response format; in essence, they often lose the "flavour of the response". Respondents

often want to qualify their answers. By allowing frequent space for comments, the author attempted to overcome this disadvantage.

2.2.2 Content of the questionnaire

The questionnaire comprised a series of closed answer questions with additional space for free text comments. Questions explored:

- the perceptions of obstetricians regarding the relationship between episiotomy and anal sphincter injury at OVD - by instrument (forceps and vacuum extraction)
- instrument preference in arrested labour at differing stations and positions of the fetal head which necessitated OVD
- the operator's usual approach to episiotomy use, whether routine or restrictive, by instrument at OVD
- operator willingness to participate in an RCT of routine versus restrictive use at OVD

Response options were categorical. In part one for example, participants were asked to indicate if they would use vacuum extraction or forceps in mid and low cavity arrest, a fetal OA position and no signs of cephalopelvic disproportion or fetal distress "always" "frequently" "rarely" or "never". These terms were not defined. Similarly, part two asked was the practitioner's current practice regarding episiotomy use "routine", "restrictive" or "never used", differentiated by the instrument used. The response "not applicable" was possible if the operator never used that particular instrument. Part three was concerned with the willingness of participants to take part in an RCT of routine versus restrictive use of episiotomy at OVD.

Obstetrician demographics were collected to enable planned subgroup analyses to explore any differences in response by gender or level of operator experience. The questionnaire was piloted on ten obstetricians of varying grades of appointment in the author's hospital for face and content validity. This informed small changes in the format of the questionnaire.

2.2.3 Participant approach

As the choice of instrument and decision whether or not to cut an episiotomy are left to the individual operator, a study of the practice of individual obstetricians rather than lead labour ward clinicians providing an overview of their unit's approach was considered more appropriate. A database of all consultants and specialist registrars in years one to five and beyond of training in the UK and Ireland who were registered with the RCOG, London was obtained from the college (Appendix 5).

As the RCOG database contained details of practitioners who may have no labour suite practice, to facilitate estimation of the total study population and establish eligibility, any recipient who felt that the questionnaire was not relevant to their current practice was asked to indicate this by means of a tick box, provide a reason why, and return the uncompleted questionnaire.

The study was undertaken during the autumn of 2004. The postal questionnaire, accompanied by a covering letter (Appendix 6) explaining the aims of the study and a pre paid return envelope to aid response was sent to all clinicians on the database. Recipients who had not returned the questionnaire within four weeks, were sent a reminder letter (Appendix 7) and a replacement questionnaire. A final reminder and questionnaire were sent with failure to respond being accepted as a wish not to participate in the survey.

2.2.4 Statistical analysis

Analysis was performed using Statistical Package for Social Scientists (SPSS) Version 11.0 for windows. Data are presented as descriptive statistics with Chi-squared tests for differences in proportions. Significance is reported as $p<0.05$. Planned sub group analyses were performed to establish any differences in response by gender or grade of respondent. To report differences between multiple options a category was chosen as reference for comparison.

2.2.5 Funding and ethical approval

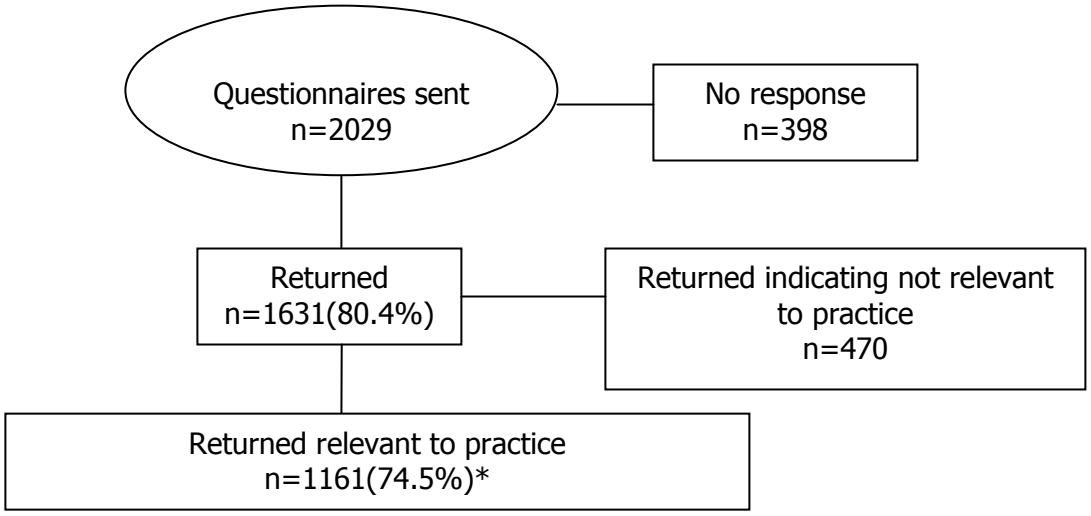
Funding for this study was provided by an Anonymous Trust Grant from Tayside Universities Hospital Trust. The local research ethics committee advised that a formal ethical evaluation of the study was not required although an appraisal of the survey was undertaken by the RCOG prior to the supply of its database.

2.3 Results

2.3.1 Response rate

Two thousand and twenty nine questionnaires were sent to consultants and trainees in obstetrics and gynaecology as provided by the RCOG database. A response rate of 80.4% was achieved (n=1631). A proportion of responses (n=470) indicated the questionnaire was not relevant to their practice. The reasons cited for non completion of the questionnaire were that the responder had no obstetric practice, did not perform OVD or the questionnaire was returned by the Royal Mail marked "addressee gone away". A total of 1161 (74.5%) questionnaires were included in the analysis (Figure 2.1).

Figure 2.1 Response rate of postal questionnaire survey



* denominator = 1559 [questionnaires sent (n=2029) – returned indicating not relevant to practice(n=470)]

2.3.2 Missing data

As missing data did not exceed 5% in all but four possible responses (instrument choice in mid cavity arrest of labour with a malposition of the fetal head) a complete case analysis was carried out.

2.3.3 Characteristics of the study population

The demographic characteristics of the respondents are reported in Tables 2.1, 2.2 and 2.3.

Table 2.1 Grade of respondents

	n=	%
Consultant	848	73.0
SpR[1] 4 - 5+	196	16.9
SpR 1 - 3	85	7.3
SSHO	3	0.3
Associate Specialist	3	0.3
Staff Grade	19	1.6
Clinical research fellow	1	0.1
Not stated	6	0.5

1 Specialist registrar (SpR)

Table 2.2 Gender of respondents

	n=	%
Men	674	58.0
Women	472	40.7
Not stated	15	1.3

Table 2.3 Age of respondents

	n=	%
<30	5	0.4
30-39	352	30.3
40-49	463	39.9
50-59	260	22.4
≥60	72	6.2
Not stated	9	0.8

2.3.4 *A priori* views on the relationship between episiotomy and anal sphincter tears

An exploration of *a priori* views held by clinicians regarding the perceived relationship between episiotomy use and anal sphincter tears at OVD was performed. The majority of respondents held the view that episiotomy use decreases the likelihood of anal sphincter tears in forceps delivery (65.5% decreases risk vs 17.9% no difference, p< 0.001). The perceived relationship in vacuum extraction deliveries appeared much more in equipoise (44.5% decreases risk vs 41.1% no difference, p=0.22). Less than ten per cent held the view that episiotomy use in both forceps and vacuum extraction increased the risk of extensive perineal tears. Less than 7% of respondents indicated that they were unsure about the relationship between episiotomy and anal sphincter tears (Table 2.4).

Table 2.4 *A priori* views on the relationship between use of episiotomy and anal sphincter tears at OVD

	Increases risk n(%)	Decreases risk n(%)	No difference n(%)	Don't know n(%)	p= [1]
Forceps	114 (9.9)	766 (65.5)	206 (17.9)	65 (5.6)	<0.001*
Vacuum	75 (6.5)	516 (44.9)	477 (41.5)	80 (7.0)	0.22

1 chi squared test for differences in proportion between "decreases risk" and "no difference"

* significant, p< 0.05

On sub-group analysis by grade of operator, no differences in beliefs were found when comparing consultants and experienced registrars (year four or above) in respect of forceps and vacuum delivery or when comparing experienced registrars (year four or above) with less experienced registrars (year one to three) with either instrument.(Table 2.5).

Table 2.5 *A priori* views on the relationship between use of episiotomy and anal sphincter tears at OVD by grade of respondent

		Decreases risk n(%)	No difference n(%)	p =[1]
Forceps	Consultant	562 (66.8)	141 (16.8)	0.27
	SpR 4-5+	143(65.6)	44(20.2)	1.00§
	SpR 1-3	58(65.9)	20(22.7)	0.76
Vacuum	Consultant	385 (45.9)	57 (6.8)	0.11
	SpR 4-5+	93(42.9)	101(46.5)	1.00§
	SpR 1-3	36(40.9)	42(47.7)	1.00

§ Category assigned as reference for comparison

1 chi squared test for differences in proportion between "decreases risk" and "no difference"

* significant, p< 0.05

Note – not all respondents stated their grade of appointment. Valid percentages are reported

When sub-group analysis was conducted by gender of operator, at forceps delivery, men and women were equally likely to believe that episiotomy use decreases the risk of an anal sphincter tear occurring (Table 2.6). Of the group reporting a belief that episiotomy use increases the risk of an anal sphincter tear occurring, men were significantly more represented.

At vacuum extraction, men were significantly more likely than women to believe episiotomy use decreases the risk of an anal sphincter tear. There were no differences in terms of gender between the small numbers who believed episiotomy use increases the risk of an anal sphincter tear occurring.

Table 2.6 *A priori* views on relationship between use of episiotomy and anal sphincter tears at OVD by gender of respondent

		Men n(%)	Women n(%)	p =[1]
Forceps	Increases risk	78 (11.6)	34 (7.3)	0.03*
	Decreases risk	446 (66.6)	311 (66.5)	0.48
	No difference	107 (16.0)	96 (20.5)	1.00§
	Don't know	39 (5.8)	27 (5.8)	____
Vacuum	Increases risk	46 (6.9)	28 (6.0)	0.14
	Decreases risk	333(49.7)	175 (37.6)	<0.001*
	No difference	250(37.3)	222 (47.7)	1.00§
	Don't know	41 (6.1)	40 (8.6)	____

1 chi squared test for differences in proportion

§ "no difference" allocated as reference category

* significant, p< 0.05

Note – not all respondents stated their gender. Valid percentages are reported

2.3.5 Instrument preference in arrested labour at differing stations and positions of the fetal head

Instrument preference varied according to the station and position of the fetal head. In non rotational delivery, vacuum extraction was preferred by the majority of respondents for low cavity procedures (82% use vacuum always/frequently vs 35% use forceps always/frequently, p<0.001) (Table 2.7). Similarly for non rotational midcavity deliveries vacuum was the preferred instrument (64% use vacuum extraction always/frequently vs 56% use forceps always/frequently, p<0.001).

Table 2.7 Instrument preference for non rotational delivery

	Vacuum Always/Frequently n (%)	Forceps Always/Frequently n (%)	p= [1]
Low cavity arrest	933 (81.6)	392 (35.3)	<0.001*
No Response	17 (1.5)	51 (4.4)	___
Mid cavity arrest	714 (63.6)	626 (55.8)	<0.001*
No Response	38 (3.3)	40 (3.4)	___

1 chi squared test for differences in proportions comparing used always/frequently with rarely/never

* significant, p< 0.05 Valid percentages are reported

In rotational mid cavity delivery there was no statistically significant differences found between instrument preferences (69% use rotational vacuum always/frequently vs 36% use manual rotation followed by traction forceps always/frequently vs 34% use rotational forceps always/frequently, p=0.11 and p=0.62 respectively). 16% of repondents would proceed directly to CS in these circumstances (Table 2.8).

Table 2.8 Instrument preference for rotational delivery

	Used Always/Frequently n= (%)	Used Rarely/never n= (%)	p= [1]	No Response n= (%)
Rotational Vacuum	745 (68.9)	336(31.1)	0.11	80 (6.9)
Rotational Forceps	366 (34.4)	697(65.6)	0.62	98 (8.4)
Manual rotation + Forceps	341 (36.2)	601(63.8)	1.00§	219 (18.9)
Caesarean Section	131(15.7)	706(84.3)	0.17	324(27.9)

§ Category assigned as reference for comparison

1 chi squared test for differences in proportions comparing used always/frequently with rarely/never

* significant, p< 0.05 Valid percentages are reported

On sub group analysis by grade of respondent, in low cavity arrest with no malposition of the fetal head, consultants were significantly more likely than SpRs 4-5 to use forceps always/frequently (low cavity forceps, 40.9% consultants vs 19.2% SpRs 4-5, p<0.001). A similar picture was seen at mid cavity arrest with no malposition of the fetal head (mid cavity forceps 60.0% consultants vs 42.0% SpRs 4-5, p<0.001) (Table 2.9). When SpRs were compared by stage of training they were found to be homogenous with regard to instrument preference.

Table 2.9 Instrument preference at non rotational delivery in relation to grade of respondent

		Vacuum Always/Frequently n= (%)	Forceps Always/Frequently n= (%)	p= [1]
Low cavity arrest	Consultant	643(76.7)	332(40.9)	<0.001*
	SpR 4-5	205(95.3)	40(19.2)	1.00§
	SpR 1-3	81(94.2)	19(22.4)	0.55
Mid cavity Arrest	Consultant	487(59.2)	490(60.0)	<0.001*
	SpR 4-5	162(76.4)	89(42.0)	1.00§
	SpR 1-3	60(72.3)	46(53.5)	0.07

§ Category assigned as reference for comparison

1 chi squared test for differences in proportions between used always/never vs rarely/never

* significant, p< 0.05

Note – not all respondents stated their grade of appointment. Valid percentages are reported

At rotational delivery, consultants were significantly more likely to use rotational forceps always/frequently than SpRs 4-5 (40.9% vs 19.2%, p<0.001) (Table 2.10). Groups were similar in their use of manual rotation and traction forceps for mid cavity rotational deliveries (consultants 36.0% vs SpR 4-5 38.2%, p=0.58) (Table 2.10). Some respondents in junior grades reported that they had not been trained in the use of rotational forceps

and in some units their use was contrary to unit policy. No differences were found when comparing more experienced SpR 4-5 with less experienced SpR 1-3 with the exception of the decision to proceed directly to CS. Consultants and experienced registrars were significantly less likely than inexperienced registrars to proceed directly to CS for delivery in a mid cavity arrest of labour with fetal malposition (15.4% vs 34.7%, p=0.001).

Table 2.10 Instrument preference at rotational delivery in relation to grade of respondent

	Rotational Vacuum Always/Frequently n= (%)	p= [1]	Rotational Forceps Always/Frequently n= (%)	p= [1]
Consultant	508(65.2)	<0.001*	319(40.9)	<0.001*
SpR 4-5	166(77.9)	1.00§	38(19.2)	1.00§
SpR 1-3	67(80.7)	0.60	8(10.0)	0.06
	Manual rotation + forceps Always/Frequently n= (%)		Caesarean Section Always/Frequently n= (%)	
Consultant	244(36.0)	0.58	77(13.1)	0.45
SpR 4-5	71(38.2)	1.00§	26(15.4)	1.00§
SpR 1-3	25(33.3)	0.46	26(34.7)	0.001*

§ Category assigned as reference for comparison

1 chi squared test for differences in proportions between used always/never vs rarely/never

* significant, p< 0.05

Note – not all respondents stated their grade of appointment. Valid percentages are reported

Subgroup analysis by gender demonstrated a significant preference among female respondents for vacuum use at all stations and positions of the fetal head and manual rotation followed by traction forceps use for rotational mid cavity deliveries. Among male

respondents there was a significant preference for low cavity forceps (42.7% vs 24.7%, p<0.001) and mid cavity rotational forceps (39.4% vs 26.6%, p<0.001). (Table 2.11)

Table 2.11 Instrument preference in relation to gender of respondent

	Men n= (%)	Women n= (%)	p=[1]
Low cavity arrest -OA position			
Vacuum Always/Frequently	505 (76.3)	415 (88.7)	<0.001*
Forceps Always/Frequently	276 (42.7)	111 (24.7)	<0.001*
Mid cavity Arrest OA position			
Vacuum Always/Frequently	387 (59.4)	317 (69.4)	0.001*
Forceps Always/Frequently	370 (56.9)	247 (54.2)	0.36
Mid cavity Arrest OT/OP position			
Rotational vacuum Always/Frequently	395 (63.9)	340 (75.9)	<0.001*
Manual rotation + Forceps Always/Frequently	172 (32.5)	164 (40.9)	0.008*
Rotational forceps Always/Frequently	246 (39.4)	113 (26.6)	<0.001*
Caesarean Section Always/Frequently	77 (16.3)	51 (14.4)	0.47

1 chi squared test for differences in proportions

* significant, p< 0.05

Note – not all respondents stated their gender . Valid percentages are reported

2.3.6 Approach to episiotomy use

A statistically significant preference for restrictive use of episiotomy was reported with both non rotational vacuum extraction (85.7% restrictive vs 12.1% routine, p<0.001) and rotational vacuum extraction (71.7% restrictive vs 27.8% routine, p<0.001). In contrast, a statistically significant preference for a routine approach to the use of episiotomy was

reported for non rotational mid cavity forceps deliveries (26.5% restrictive vs 73.2% routine, p<0.001) and rotational mid cavity forceps deliveries (18.6% restrictive vs 80.4% routine, p<0.001). In low cavity forceps delivery the approach to use of episiotomy was in equipoise (47.8% restrictive vs 51.3% routine, p=0.23). Very few respondents claimed to never use episiotomy (range 0.3 – 2.2%) (Table 2.12).

Table 2.12 Approach to use of episiotomy at OVD by instrument

	Routine use n(%)	Restrictive use n(%)	p= [1]	Never use n(%)
Non rotational vacuum extraction	134 (12.1)	945 (85.7)	<0.001*	24 (2.2)
Rotational vacuum extraction	286 (27.8)	739 (71.7)	<0.001*	9 (0.9)
Low cavity forceps	586 (51.3)	546 (47.8)	0.23	10 (0.9)
Non rotational mid cavity forceps	815 (73.2)	295 (26.5)	<0.001*	3 (0.3)
Rotational mid cavity forceps	622 (80.4)	144 (18.6)	<0.001*	8 (1.0)

1 chi squared test for differences in proportion between routine and restrictive use

* significant, p< 0.05

Denominator is those respondents who use mode of delivery. Valid percentages are reported.

Analysis by grade of respondent suggested that although a routine use of episiotomy was the preferred approach for non rotational forceps delivery increasing experience was associated with a greater likelihood of a restrictive approach being adopted (low cavity non rotational forceps delivery: consultants 52.1% vs SpR 4-5 41.4%, p=0.005 vs SpR 1-3 22.7%, p= 0.002 and mid cavity non rotational forceps delivery: consultants 29.4% vs SpR 4-5 23.1%, p=0.07 vs SpR 1-3 7.2%, p= 0.002) (Table 2.13). The approach to episiotomy use at non rotational vacuum and rotational forceps was similar across the experience spectrum. At rotational vacuum extraction there were no differences between the approach adopted by consultants and SpR 4-5 however SpR 1-3 were significantly

more likely to adopt a routine approach to episiotomy use (SpR 4-5 28.0% vs SpR 1-3 40.7%. p=0.04).

Table 2.13 Approach to use of episiotomy at OVD by instrument used and grade of respondent

		Routine use n(%)	Restrictive use n(%)	p= [1]
Non rotational vacuum	Consultant	95(12.0)	677(85.6)	0.45
	SpR 4-5	23(10.6)	191(87.6)	1.00§
	SpR 1-3	14(15.9)	73(83.0)	0.28
Rotational vacuum extraction	Consultant	188(25.8)	532(73.1)	0.65
	SpR 4-5	60(28.0)	153(71.5)	1.00§
	SpR 1-3	35(40.7)	51(59.3)	0.04*
Low cavity forceps	Consultant	391(46.9)	434(52.1)	0.005*
	SpR 4-5	124(57.7)	89(41.4)	1.00§
	SpR 1-3	68(77.3)	20(22.7) .	0.002*
Mid cavity non rotational forceps	Consultant	575(70.4)	240(29.4)	0.07
	SpR 4-5	160(76.9)	48(23.1)	1.00§
	SpR 1-3	76(91.6)	6(7.2)	0.002*
Rotational forceps	Consultant	495(79.1)	125(20.0)	0.17
	SpR 4-5	89(84.8)	15(14.3)	1.00§
	SpR 1-3	36(90.0)	3(7.5)	0.27

§ Category assigned as reference for comparison

1 chi squared test for differences in proportion between routine and restrictive use

* significant, p< 0.05

Denominator is those respondents who use mode of delivery.

Note – not all respondents stated their grade of appointment. Valid percentages are reported

Analysis by gender of respondent revealed that at non rotational vacuum extraction, men preferred a routine approach to episiotomy use (men 14.6% vs women 8.5%, p=0.002), whereas, women preferred a restrictive approach (men 83.0% vs women 89.5%, p=0.002) (Table 2.14). This preference was reversed when low cavity forceps were used, with men preferring a restrictive approach to episiotomy use (men 50.4% vs women 44.2%, p=0.04) and women a routine approach (men 48.6% vs women 55.2%, p=0.03). There were no differences at rotational vacuum extraction, mid cavity non rotational forceps or rotational forceps delivery or in the small numbers who stated they never used episiotomy.

Table 2.14 Approach to use of episiotomy by gender of respondent.

		Men n(%)	Women n(%)	p= [1]
Non rotational vacuum extraction	Routine use	92(14.6)	39(8.5)	0.002*
	Restrictive use	523(83.0)	410(89.5)	
	Never use	15(2.4)	9(2.0)	
Rotational vacuum extraction	Routine use	164(28.1)	118(27.1)	0.71
	Restrictive use	412(70.7)	316(72.5)	
	Never use	7(1.2)	2(0.5)	
Low cavity forceps	Routine use	321(48.6)	257(55.2)	0.03*
	Restrictive use	333(50.4)	206(44.2)	
	Never use	7(1.1)	3(0.6)	
Mid cavity non rotational forceps	Routine use	464(72.0)	343(75.2)	0.24
	Restrictive use	178(27.6)	112(24.6)	
	Never use	2(0.3)	1(0.2)	
Rotational forceps	Routine use	371(79.1)	244(83.0)	0.19
	Restrictive use	95(20.3)	45(15.3)	
	Never use	3(0.6)	5(1.7)	

1 chi squared test for differences in proportion between routine and restrictive use

* significant, $p < 0.05$

Denominator is those respondents who use mode of delivery.

Note – not all respondents stated their gender. Valid percentages are reported.

Significant differences were found in approach to episiotomy use with all instruments between respondents of differing *a priori* views on episiotomy use. Those respondents who believed that episiotomy use decreased the risk of anal sphincter tears occurring were

significantly more likely to have a routine approach to episiotomy use (Table 2.15). Those who believed it made no difference to the risk were significantly more likely to have a restrictive approach to episiotomy use. Interestingly of respondents who believed that episiotomy use increased the risk of anal sphincter tears were equally as likely to have a routine approach to episiotomy use as a restrictive approach.

Table 2.15 Approach to episiotomy use according to *a priori* views on the relationship between episiotomy use and anal sphincter tears

		Routine use n(%)	Restrictive use n(%)	p= [1]
Non rotational vacuum extraction	Decreases risk	107(79.9)	377(39.9)	<0.001*
	Increases risk	6(4.5)	62(6.6)	0.16
	No difference	13(9.7)	432(45.7)	1.00§
Rotational vacuum extraction	Decreases risk	191(66.8)	257(34.8)	<0.001*
	Increases risk	11(3.8)	57(7.7)	0.94
	No difference	71(24.8)	358(48.4)	1.00§
Low cavity forceps	Decreases risk	420(71.7)	329(60.3)	<0.001*
	Increases risk	58(9.9)	52(9.5)	0.14
	No difference	76(13.0)	123(22.5)	1.00§
Mid cavity non rotational forceps	Decreases risk	586(71.9)	147(49.8)	<0.001*
	Increases risk	78(9.6)	26(8.8)	<0.001*
	No difference	108(13.3)	91(30.8)	1.00§
Rotational forceps	Decreases risk	439(70.6)	73(50.7)	<0.001*
	Increases risk	52(8.4)	20(13.9)	0.77
	No difference	92(14.8)	39(27.1)	1.00§

1 chi squared test for differences in proportion * significant, p< 0.05

2.3.7 Willingness to participate in an RCT of routine vs restrictive use of episiotomy at OVD

Seven hundred and twenty eight (65.4%) respondents expressed a willingness to participate in an RCT of routine vs restrictive use of episiotomy at OVD (Table 2.16).

Table 2.16 Willingness to participate in an RCT

Yes n(%)	No n(%)	Unsure n(%)
728(65.4)	321(28.8)	64(5.7)

On further analyses by gender and grade of respondent, men were significantly less likely to be willing to participate than women (men 56.6% vs women 73.4%, p<0.001) and respondents reported significantly less willingness to participate with increasing grade of practitioner (Tables 2.17, 2.18).

Table 2.17 Willingness to participate in an RCT by gender of respondent

	Men n(%)	Women n(%)	p= [1]
Yes	377(56.6)	343(73.4)	<0.001*
No	213(32.0)	100(21.4)	
Unsure	76(11.4)	24(5.1)	

1 chi squared test for differences in proportion between yes and no

* significant, p< 0.05

Note – not all respondents stated their gender. Valid % are reported.

Table 2.18 Willingness to participate in an RCT by grade of respondent

	Consultant n(%)	SpR+others n(%)	p= [1]	SpR 4-5+ n(%)	SpR 1-3 n(%)	p= [1]
Yes	486(58.1)	238(77.8)	<0.001*	165(75.7)	73(83.0)	0.08*
No	269(32.2)	49(16.0)		40(18.3)	9(10.2)	
Unsure	81(9.7)	19(6.2)		13(6.0)	6(6.8)	

1 chi squared test for differences in proportion between yes and no

* significant, p< 0.05

Note – not all respondents stated their grade of appointment. Valid % are reported.

2.3.8 Analysis of free text responses to questions

657(56.7%) of responses contained free text responses. This highlights the restraints respondents feel when completing a questionnaire due to the rigidity of its format and their wish to expand on the answers they provide. This may also reflect the complex nature of the decision making process an operator employs when deciding which instrument to use and whether or not to perform an episiotomy.

Free text responses highlighted a diversity of opinion. The account presented below reports the categories that emerged from a thematic analysis of these data.

2.3.8.1 Instrument preference

Clinical factors which influence instrument choice

Instrument preference is clearly an individual choice and is not prescribed. There appears to be a plethora of factors which clinicians take into account in their decision making.

Some respondents were influenced by the aim of avoiding sequential instrument use:

" I know I will be successful with forceps and want to avoid 'forceps assisted vacuum' "

Many respondents commented that decisions were based on a variety of factors e.g. parity, patient preference, maternal effort, epidural anaesthesia, fetal size, caput, moulding, position and level of presenting part:

"*The approach to all these scenarios is relative, multifactorial and depends on assessment at the time*"

Others seemed more limited in their practice whether due to hospital policy, practicalities or personal beliefs:

"*rotational forceps not available in my hospital"*

"dependant on instruments in stock"

"*I do not think there is a place for midcavity instrumental delivery in contemporary obstetric practice"*

Operator expertise

In accordance with the RCOG's Green top guideline, operator expertise has a substantial bearing on instrument preference as reflected by comments:

"*Unable to manually rotate effectively"*

"*We are dealing with a generation of trainees who lack experience in mid cavity deliveries"*

"I have not used rotational forceps for a long time now"

"not trained in ventouse"

Training also had an influence both for the trainer and trainee:

"*As a junior I try to use forceps and ventouse*"

"*Everyone should be taught to use either*"

2.3.8.2 Use of episiotomy

Clinicians beliefs which influence episiotomy use

"*I still feel a tear during instrumental delivery seems like carelessness - an episiotomy correctly performed seems like good practice*"

2.3.8.3 Willingness to participate in an RCT

Validity and practicality of conducting of an RCT

A full range of responses were received on this theme ranging from:

"*a worthwhile study*"

"*excellent trial to participate in*"

" *restrictive versus routine episiotomy will help us much in practice*"

to

"*trial not justified*"

"*need to demonstrate equipoise*"

"*results would be nongeneralisable and difficult to adjust for confounding factors*"

Some responses reflected an element of research fatigue and time constraints

"*too old*"

"*not very interested in obstetrics*"

" *too much paperwork*"

"*not the energy to get involved in another trial*"

One respondent stated he would need to see a detailed protocol before he could comment, whilst another said his response would depend on the planned level of support to be provided by the study team.

Preconceived ideas about episiotomy use and current practice

"*Clinician's prior belief about the value of episiotomy is variable and may determine willingness to recruit to such a study in general and in individual circumstances*"

The above statement summarises nicely the effect of preconceived ideas and the variation in operator current practice on responses. Some respondents were willing to participate only in certain circumstances:

"*for forceps only*"

" *only for vacuum*"

"*restrictive episiotomy should not be applied if indication is fetal distress*"

Current practice influenced response and in some cases practitioners were unwilling to be randomised to a specific approach to episiotomy use:

"*not interested – feel my results are good enough*"

" *done part of my specialist training in a country where routine episiotomy is practised. Haven't seen as bad tears as in UK*"

"*always use episiotomy with ventouse and prim*"

"*routine practice because trained that way*"

" *prefer individualised clinical practice*"

Ethical issues surrounding the conduct of an RCT

Concerns were expressed with regard to the ethical considerations of an RCT of episiotomy use at OVD. Some respondents were unwilling to decide on an individual basis whether to take part or not and deferred the decision to their unit. Concern was expressed about the long term implications of the trial on the participant's pelvic floor if an episiotomy was not performed or if an "unnecessary" episiotomy were performed:

"*restrictive not justifiable*"

Another…

"*routine episiotomy not justifiable, not justifiable for multips*"

One respondent raised the issue of bias in the trial results:

"*As consultant, I do relatively few instrumental deliveries these days but those I do are likely to be considered potentially more difficult. I trained in the era of forceps before ventouse, there will be bias introduced as forceps are being used for the more difficult cases*"

2.4 Discussion

This national survey achieved a very good response rate (75%), representing a wide spectrum of obstetricians in practice throughout the United Kingdom and Ireland. "Adequate response rates" appear to vary from expert to expert. Fowler recommended 75% as a minimum acceptable response rate whereas Mangione categorised postal survey response rates as excellent (>85%), very good (70-84%), acceptable (60-69%), barely acceptable (50-59%) and below 50% as unacceptable. Asch et al. (1997) found the mean response rate among surveys conducted in the US and reported in American medical journals was only 60% and for published surveys of physicians the rate was even lower at 54% (All as cited in McColl et al. (2001).

There did not appear to be any difficulty in completing the questionnaire with less than 5% data missing for the majority of responses (17/21). The free text responses enhanced the quality of information provided and suggested that key issues had not been overlooked.

The RCOG database had its limitations. The database relies on obstetricians notifying the RCOG of a change of address or practice and updating of records by the RCOG (addresses provided were a mixture of home and hospital) and did not differentiate between those with and without obstetric practice. Despite these drawbacks, it was thought to be the most accurate tool available. Clearly with any survey of this type there is a possibility that the non-respondents may hold views that are at strong variance with the study findings.

Instrument preference was found to vary both with the station and position of the fetal head and with the level of experience and gender of the operator. Vacuum extraction was found to be the preferred approach in both low cavity and rotational mid cavity operative vaginal deliveries. In Scotland, statistics show that while the overall OVD rate has remained quite constant over the last few decades, the forceps rate has fallen from 13% in 1981 to 7.0% in 2000 though the vacuum extraction rate increased from 0.4% in 1981 to almost 6.0% in 2000 (NHS Scotland 2003). The survey findings reflect the shift towards the use of vacuum extraction especially by operators who are less experienced. Registrars were found to be significantly more likely to use vacuum than consultants at all stations and positions of the fetal head. Preference for vacuum was also noted among women respondents which may be a reflection on the demographics of the sample, and possibly the profession, with more women among the less experienced ranks and more men among consultants. This trend in the use of vacuum extractor is supported by evidence from the Cochrane systematic review by Johanson and Menon (1999) which suggests that where OVD is required vacuum extraction should be the instrument of first choice. Guidance from the RCOG (Green top guideline No 26, 2011) however suggests a more prudent approach, selecting the instrument most suited to the clinical situation and within the operator's expertise as there are risks and benefits associated with both.

Clinicians' perceptions regarding the relationship between the use of episiotomy and the occurrence of anal sphincter tears would appear to support the historical view that episiotomy is protective of anal sphincter trauma at forceps delivery but would appear to be more equivocal about the relationship at vacuum extraction. Despite the paucity of rigorous data on the relationship between episiotomy and the occurrence of anal sphincter tearing at OVD, 93% of clinicians responded with a firm perception of the relationship with the majority of views expressed being in contrast to the limited evidence presented from the research available to date on this aspect of OVD. Less than ten per cent held the view supported by the published literature at the time of the survey, for the most part, that episiotomy use in both forceps and vacuum extraction increased the risk of extensive perineal tears. Evidence from the literature is unclear regarding the relationship between the use of episiotomy and the occurrence of anal sphincter tears. This apparent contradiction between the evidence and clinicians perceptions suggests further more robust examination of this topic is required to provide doctors with reliable information on which they can base their practice. This recommendation for further research was emphasised in the RGOC Green top guide line No 26, Operative vaginal delivery (2011). Such evidence would be best achieved by the conduct of an RCT of restrictive versus routine use of episiotomy at OVD.

As one might expect these *a priori* views are reflected in current practice with regard to episiotomy use at OVD. A restrictive use of episiotomy was found to be the respondents preferred approach at vacuum delivery and a routine use at forceps delivery. There is compelling evidence that a restrictive approach to episiotomy use is preferential in SVD to lower the risk of posterior perineal trauma, need for suturing and healing complications (Carroli and Belizan 1999). This evidence has resulted in a marked change in midwifery practice surrounding normal vaginal delivery but no such evidence exists to support either

approach to episiotomy use at OVD. No RCTs have been conducted to date to provide such evidence but the necessity of such a trial was identified by Carroli and Belizan who suggested it in 1999 as a priority for future research.

The findings of this survey on subgroup analysis by grade and gender of operator further support the necessity for such a trial as it is evident that practice varies depending on level of experience. Data suggest that more experienced clinicians, who are more proportionately male, prefer forceps use to vacuum at all stations and positions of the fetal head and are more likely to believe that episiotomy is protective of anal sphincter tears. Less experienced operators are more likely to prefer vacuum use at all stations and positions of the fetal head and to proceed to CS in the case of mid cavity malpostion of the fetal head requiring operative delivery. Data also suggest that the more experienced the operator the more likely they are to adopt a restrictive approach to the use of episiotomy in rotational vacuum and all types of forceps delivery whilst the approach in non rotational vacuum was similar across the experience spectrum. This identified variation in practice is not based on rigorous evaluation of the different approaches to episiotomy use at OVD, a situation which should be rectified to achieve the gold standard of evidence based practice.

The respondents to this survey expressed significant interest in a potential RCT although some respondents felt that this was an issue for clinical judgement and could not be tested in a trial setting.

In conclusion, the findings of the survey identified a wide variation in approach to OVD and practice surrounding episiotomy use at OVD which is not supported by current evidence in the literature. The potential of obtaining such evidence through the conduct of an RCT of routine versus restrictive use of episiotomy at OVD was supported by the majority of respondents to this survey.

Chapter 3 - A Feasibility Study Of An RCT Of Routine Versus Restrictive Use Of Episiotomy At Operative Vaginal Delivery

3.1 Introduction

This chapter describes a feasibility study of an RCT of routine use of episiotomy versus restrictive use of episiotomy at OVD. In the national survey of obstetricians in the UK and Ireland more than half of the respondents supported the need for an RCT to address the question of episiotomy use at OVD. Some respondents however felt that this was an issue for clinical judgement and could not be tested in a trial setting. The review of the literature established that operator's beliefs can influence willingness to randomise women in an RCT of episiotomy use at normal vaginal delivery (Klein et al. 1995). This had important implications for the proposed trial. Because of this and the known complexities of conducting intrapartum research it was felt necessary, prior to conducting a larger scale pilot RCT, to test the design, feasibility and acceptability of such a trial to operators and women in a small feasibility study.

3.1.1 Feasibility study aims

The aims of this feasibility study were to assess the acceptability and practical issues of conducting an RCT of restrictive versus routine use of episiotomy at OVD. An additional aim was to evaluate the feasibility and acceptability of collecting follow up data, up to six weeks postpartum, by means of participant completed questionnaires and perineal assessment.

To achieve these aims it was planned:

- To develop the data collection tools required to elicit maternal and neonatal health outcomes following delivery and test them in a clinical setting

- To develop follow up questionnaires to assess the maternal morbidity outcome measures – urinary incontinence, faecal incontinence, perineal pain, sexual and psychological morbidities – at baseline, on the first postnatal day and at six weeks postpartum
- To assess acceptability of such a study to operators and study participants
- To inform a sample size calculation for the proposed pilot RCT of routine versus restrictive use of episiotomy at OVD

3.2 Methods

3.2.1 Study design

This feasibility study was designed as a pragmatic, hospital based, parallel group trial with 1:1 randomisation by individual, comparing the routine use of episiotomy with a restrictive use of episiotomy at OVD.

3.2.2 Justification for choice of study design

Treweek and Zwarenstein (2009) in their commentary on "Making trials matter" described a pragmatic approach to study design as involving clinicians and participants for whom the study intervention is relevant in real life, using the current accepted treatment as a comparator and involving no other staff or financial resources than are normally available to the situation.

The national survey of clinical practice described in chapter two revealed that in the UK and Ireland both a routine and restrictive use of episiotomy is employed at OVD. As both approaches are in common use it is justifiable and desirable to compare one against the other to provide women and their carers with robust evidence on which to base their decision making. Of respondents to the questionnaire, 65% expressed a willingness to

participate in an RCT of approach to episiotomy use at OVD which is indicative of the relevance of this topic to their day to day practice.

3.2.3 Setting

The study was conducted in Ninewells Hospital, Dundee. It is a large tertiary level teaching hospital. Local statistics for 2004 (unpublished) revealed there were 3188 confinements, 452 (14.2%) of which were by OVD and an episiotomy rate of 22% (SVD and OVD). The episiotomy rate was 85.4% at OVD - 92.4% at forceps assisted delivery and 69.6% at vacuum assisted delivery reflecting the findings of the national survey of obstetricians where a routine approach to episiotomy use was more common in forceps deliveries and a more restrictive approach at vacuum extraction.

3.2.4 Participants

Eligible participants were nulliparous or multiparous women who had a live, singleton fetus with cephalic presentation at term (≥37 weeks gestation) and for whom an OVD was recommended by the attending obstetrician.

Inclusion/exclusion criteria limited the study population on an age basis, as ethical approval was only sought to approach women 16 years old or more. Younger mothers were, it was felt, a particularly vulnerable group who may not be able to provide truly informed consent.

Women who had a poor grasp of the English language were not approached to consider participation as no translator services were available to confirm any consent given was fully informed and there were concerns regarding the women's ability to accurately complete follow up questionnaires.

Women for whom it would be insensitive to approach to participate in the study, for example women whose baby had a known congenital anomaly or were extremely anxious due to a previous traumatic experience of childbirth, were also not invited to participate.

3.2.5 Recruitment

Recruitment to the study took place between October 2003 and April 2004. Eligible women who were more than 34 weeks pregnant were approached by the author at hospital based antenatal clinics and by community midwives in the community setting; at GP based antenatal clinics or when discussing the "Birth plan" at home. Recruitment took place during the antenatal period in order that, in line with current recommendations (AIMS 1998) and the terms of the ethics committee approval, no woman was informed of the study for the first time when she was in labour.

After face to face explanation of the study and consideration of a written participant information sheet which was retained by the participant (Appendix 8), women expressing an interest in participation were given a written consent form (Appendix 9) and a baseline questionnaire on pelvic floor symptoms (Appendix 10) for completion. Signing of the consent form was witnessed by the author or the community midwife obtaining consent. A letter of notification of study participation was sent to the woman's General Practitioner (GP) (Appendix 11).

3.2.6 Timing of participant randomisation

Women who had expressed interest in participation in the study during the antenatal period were identified by hospital-based midwives/obstetricians when they were admitted to hospital in labour by means of a sticker placed in the women's case notes at the time of receiving written consent to participation in the trial (Appendix 12). The attending

midwife/obstetrician verbally confirmed each woman's continuing consent to participation immediately prior to randomisation. Randomisation was undertaken, at the time the decision was made to attempt an OVD i.e. in the second stage of labour, by means of a locally produced web based computer program (Appendix 13).

Exclusion criteria in labour were women who:

- had not given written informed consent prior to the onset of labour
- presented with a preterm labour i.e. gestation of < 37 weeks at delivery
- had a non cephalic presentation at delivery
- who were not recommended to have an OVD

3.2.7 Randomisation

Randomisation was performed by means of a web based program accessed by a member of the participant's care team within the labour suite when a decision was made to deliver her by OVD. This methodology ensured concealment of the intervention allocation (Schultz and Grimes 2002). The program was generated using randomly permuted blocks of ten to minimise the scope for selection bias due to operators "guessing" the assignment (Matts and Lachin 1988) and was developed locally by a statistician independent of the study team. A back up system was also in place (opaque, sealed, numbered envelopes to be opened sequentially) in the case of computer/web malfunction.

Randomisation was to either:

- routine use of episiotomy (in all cases)
- restrictive use of episiotomy (only if tearing became apparent or the operator considered an episiotomy necessary)

A comparison between routine use and restrictive use rather than no use (which would be the ideal trial) was adopted as we considered it unethical to randomise to no episiotomy in case there were situations where the obstetrician considered an episiotomy to be clearly necessary. From the review of the literature regarding episiotomy use at spontaneous delivery (Carroli and Belizan, 1999) routine versus restrictive use of episiotomy would appear to be the best approach and this was supported by evidence from the national survey in which it was seen that few obstetricians would be willing to adopt a no episiotomy approach (<2% reported never using episiotomy).

It was not possible to blind the operator or participant to the allocation generated by the program.

Instructions on how to randomise women were posted beside computers in labour suite and in each delivery room to facilitate ease of randomisation (Appendix 14). The author also undertook in-service education with midwives and obstetricians working in the labour suite to familiarise them with the randomisation program. A dummy stratum of the randomisation program was available to allow operators to practise the randomisation process. This was an ongoing exercise throughout the time span of the feasibility study.

The allocation outcome was recorded in the participant's notes. On randomisation the allocation was also generated on a web based allocation log which the author cross-checked with the participants notes to ensure the correct allocation had been assigned.

3.2.8 Intervention

The primary comparison was of a routine use of episiotomy versus a restrictive use of episiotomy.

3.2.9 Outcome measures

In keeping with the pragmatic approach to the design of this trial it was intended to measure an outcome of immediate importance to participants and their carers. The review of the literature identified perineal tearing involving the anal sphincter with its associated morbidities as of prime importance when considering the optimal approach to episiotomy use at OVD. For this reason anal sphincter tearing was adopted as the primary outcome with secondary outcomes including identified high risk maternal and infant morbidities. Maternal outcomes included PPH (blood loss > 500mls); perineal pain measured by analgesic use; infection or healing complications such as perineal haematoma with or without a requirement for drainage or breakdown of the perineum requiring resuturing; urinary or faecal morbidity up to ten days postpartum. Neonatal outcomes included low Apgar scores (≤ 3 at one minute or <7 at five minutes), umbilical artery metabolic acidosis (umbilical artery pH < 7.10 or base deficit > 12.0), need for neonatal resuscitation, admission to the neonatal unit and neonatal trauma such as cephalhaematoma, retinal haemorrhage, encephalopathy, BPI, fracture or less significant bruising or laceration.

3.2.10 Data extraction

Data, extracted from maternity case notes and computerised databases, were entered on a paper pro forma (Appendix 15). To protect confidentiality datasheets were anonymised by allocating each participant a unique study number. Corresponding names were stored on a separate spreadsheet to facilitate follow-up, on a password protected computer within the Division of Maternal & Child Health Sciences at the University of Dundee with access only by the author.

3.2.11 Follow-up measures

Anonymised questionnaires were given or sent to all participants to elicit maternal morbidities that could not be sufficiently captured from case notes or the maternity database. This section describes the work undertaken in the design of this component of the study and the development of the tools appropriate to accurately capture maternal and neonatal morbidities.

3.2.11.1 Baseline and follow-up questionnaire development

Potential assessment tools of relevant maternal morbidities which were identified in chapter one of this thesis were sought in the literature and those validated tools which were thought to be most relevant to the study were identified (described in section 3.2.11.3). Self completing questionnaires were designed to incorporate the validated measurement tools of pain, urinary and faecal morbidity and emotional wellbeing. In addition to validated assessment tools, questions were included in the six week postal questionnaire exploring maternal and child health since delivery – if a doctor had been consulted was hospital admission necessary and what treatment if any had been instigated. Maternal use of antibiotics for delivery related infections was also enquired about.

The questionnaires were self completed by the participants at the time of obtaining consent to participate in the study as a baseline measure; in the first or second post partum day to assess short term morbidity (Appendix 16) and following confirmation from the participants Health Visitor that there were no contraindications to continued participation, a postal questionnaire was also sent at six weeks postpartum to elicit more persistent maternal and neonatal morbidities (Appendix 17). The postal questionnaire was accompanied by an explanatory covering letter (Appendix 18) and a pre paid self

addressed envelope to aid return. This time point was chosen to tie in with the general post natal assessment performed by the participant's GP or hospital consultant if required. If a response was not elicited a reminder letter and replacement questionnaire with prepaid return envelope were sent.

Due to the sensitive nature of the questioning, it was made clear to participants that they should feel free to leave out any question they did not feel comfortable completing. These questionnaires were piloted on women in both the antenatal and postpartum periods prior to commencement of the pilot study. They were well received by women but feedback informed minor refinements to the questionnaire design.

3.2.11.2 Perineal assessment

"REEDA", a clinical assessment tool to assess perineal health was identified as the most suitable tool to be completed prior to hospital discharge. It consists of a four point categorical score measuring components associated with the healing process which had been validated in clinical trials (Davidson 1974). It is a systematic attempt to evaluate postpartum perineal trauma evaluating redness, oedema, bruising, discharge and alignment of the perineum (Appendix 19). This assessment was made by the author on the first or second postpartum day before hospital discharge.

3.2.11.3 Questionnaire components

Urinary morbidity

Urinary continence was evaluated antenatally and at six weeks postpartum by self completion by the participant of a shortened Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire (Brookes et al. 2004), a validated tool to evaluate female lower urinary tract symptoms and their impact on QOL.

The questionnaire investigated eight components - frequency, urgency, urge incontinence, frequency of incontinence, stress incontinence, miscellaneous incontinence, what degree of protection was required to be worn by the participant and the number of changes, if any, required per day.

A five point categorical score, with zero implying complete continence and four, complete incontinence, was completed for each component. Impact on life was scored on a four point categorical scale for the first six components with zero consistent with continence posing no problem and three signifying symptoms posed a serious problem. For each participant a global urinary continence score and a global impact on life score was calculated from the aggregate of the categorical scores and the aggregate of the impact on life scores respectively.

Sexual health assessment

Simple questions related to the woman's experience of dyspareunia, its severity and impact on sexual activity were posed at baseline and six weeks postpartum.

Anal morbidity

Maternal bowel function was also assessed by a self completed Wexner score. This is a commonly used and validated tool for the assessment of faecal continence which was selected for its simplicity and ease of completion (Jorge and Wexner 1993). Participants completed this detailed bowel function questionnaire at baseline and six weeks postpartum. The score consists of five parameters – flatal incontinence, incontinence of liquids, incontinence of solids, necessity to wear protection and alteration to lifestyle - each given a five point categorical score with zero implying complete continence and four, complete incontinence. Impact on life for each component was scored on a four point

categorical scale with zero consistent with continence posing no problem and three signifying symptoms posed a serious problem. For each participant a global anal continence score and a global impact on life score was calculated from the aggregate of the categorical scores and the aggregate of the impact on life scores for the five parameters respectively.

Faecal urgency was noted and deemed significant if the participant was unable to defer defecation for longer than five minutes.

Psychological morbidity

Maternal emotional wellbeing was assessed by the administration of the EPDS at baseline, first or second day and six weeks postpartum. This tool has been validated to screen for depression in late pregnancy and the postpartum period (Josefsson et al. 2001). Current recommended practice in Tayside aims for all pregnant women to have an EPDS performed by their health visitor to identify those at greater risk of developing post natal depression. An EPDS of $\geq$ 13 was taken to signify possible psychological morbidity.

Assessment of mother's perception of pain

Perineal pain was assessed on day one or two and at six weeks postpartum by completion of a visual analogue scale (VAS) and a shortened form of the McGill pain questionnaire.

A VAS was used on which the woman transcribed her perineal pain level numerically on a scale of 0 (least imaginable pain) to 100 (worst imaginable pain). A VAS has the advantage of brevity and has been previously used without reported difficulty.

The shortened form of the McGill pain questionnaire was adopted. This is an assessment tool developed by McGill University, Toronto to provide quantitative measures of clinical pain (Melzack 1975). It uses word descriptors that the participant selects to best describe

their subjective pain experience. Descriptors are grouped into 20 categories, only one of each grouping to be selected by the participant and any category that is not relevant to the participant's experience can be omitted. The three measures derived from the McGill questionnaire are:

- The pain rating index (PRI) - an aggregate of the numerical value assigned to each descriptor chosen.
- The number of words chosen.
- The Present Pain Intensity (PPI) based on a one to five intensity scale.

Descriptors were also selected to identify the pattern and severity of the participant's pain experience.

3.2.12 Data analysis

Data were entered on to a database using SPSS version 11.0 for analysis.

Data analysis proceeded according to CONSORT guidelines for RCTs (Moher et al. 2001). Data were examined for completeness to indicate the ease of identifying primary and secondary outcome measures from case note records and to test that the REEDA inspection and self complete follow up questionnaires were fit for purpose in a clinical setting. Descriptive statistics were used to describe randomised individuals in relation to those eligible.

An intention-to-treat comparison was performed between the two groups for both primary; secondary maternal and neonatal outcomes; and follow up measures. Data is limited by the small sample size and no statistical or clinical interpretation can be placed on the findings. As this analysis does not represent one of the aims of this feasibility, data

will be presented purely as an illustration of the analysis plan set out at the development stage of this study in Appendix 32.

3.2.13 Funding and ethical approval

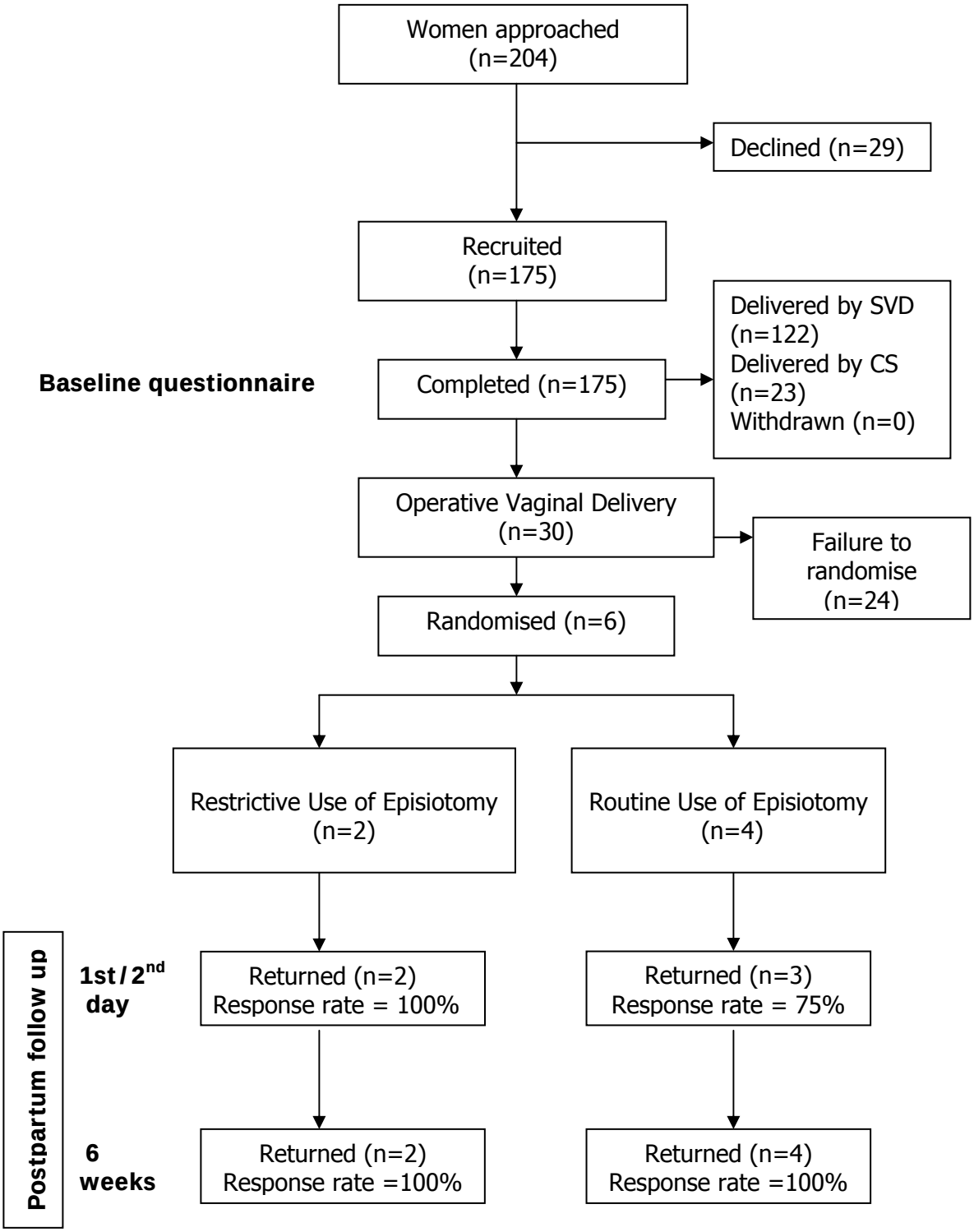
Funding for this study was provided by Tayside University Hospitals Trust Grant Scheme (R040 E505) and a favourable ethical opinion of the research was given by the Tayside Committee on Medical Research Ethics (reference number: 165/03).

3.3 Results

3.3.1 Results of feasibility study

204 antenatal women were invited to participate in the study. Of these 175(86%) provided written consent to participate in the trial should they require OVD. Thirty (17%) consented women proceeded to OVD and so became eligible for randomisation. Six (20%) of the possible cohort were randomised with no loss to follow up and outcome data available for all (Figure 3.1).

Figure 3.1 CONSORT Flowchart



The randomisation process was found to be easy to use and accessible to midwives and obstetricians caring for women undergoing OVD although there was some hesitance from operators who were less computer literate.

The data collection pro forma, developed for completion on all study participants, found data to be easily accessible in the patient's hospital case notes and computerised maternity database routinely completed by the care team during the intrapartum and immediate postpartum period (up to ten days postpartum when mothers were discharged from midwifery care).

Self complete questionnaires, developed using previously validated assessment tools identified in the literature to assess rates of maternal morbidity in the postpartum period, appeared to be easy to complete by participants as indicated by the high response rate and low level of missing data.

All women randomised received an episiotomy. Perineal assessment was achieved in all cases on the first or second day postpartum. The REEDA tool was found to be easy to use by the author and acceptable to women as perineal inspection forms part of the routine care of postnatal women. It also provided the women an additional opportunity to voice any concerns they had regarding perineal health.

In cases where delay was the indication for OVD the mean decision to delivery time was 39 minutes (range ten to 105 minutes). Women who were randomised were more likely to have had a prolonged second stage of labour than women who were not randomised (100% vs 58.3%). In women who were randomised the mean decision to delivery time was 39 minutes (range 11 to 108 minutes) compared to 30 minutes (range eight to 61 minutes) in women who were not randomised. Fetal distress was noted as the indication for OVD in seven cases, only one of which was randomised. The mean decision to delivery

time in these cases was 16 minutes (range eight to 28 minutes) and in the woman who was randomised the decision to delivery time was 18 minutes.

Non randomised women were more likely to have been delivered by rotational forceps delivery and have had a larger baby. Of the women randomised, two were delivered by non rotational mid cavity forceps, two by non rotational ventouse and two by rotational mid cavity forceps.

All women randomised were primiparous compared to 16 of 24 women (66.7%) recruited but not randomised. Women who were randomised were more likely than women who were not to have been delivered by a consultant (33% vs 0%).

3.4 Discussion

The conduct of intrapartum research is well known for its difficulties and with this in mind the feasibility study was carried out to establish the pitfalls in the study design prior to undertaking a large two centred pilot RCT. In addition funding bodies today rightly require scrutiny of a study design on a small scale prior to the commitment of large sums of money on a study design which may be flawed. This feasibility study had a number of aims. The success of achieving each of these is discussed in the remainder of this chapter.

1. To develop the data collection tools required to elicit maternal and neonatal health outcomes following delivery and to test the study design.

It was shown in this feasibility study that the development of data collection tools that were acceptable to women and healthcare professionals to elicit maternal and neonatal morbidities is possible. The REEDA tool and self completing questionnaires were found to be acceptable methodologies to study participants, facilitating a more in depth

investigation of maternal morbidities in the postpartum period than solely case note retrieval would allow.

The percentage of women eligible for randomisation in the trial but not randomised was unacceptable. Evidence from the national survey of practice (chapter 2) suggested that operators may have some difficulty cutting an episiotomy that they did not deem necessary if the participant was randomised to the routine arm of the study e.g. in multiparae or vacuum delivery where a restrictive approach to episiotomy use is favoured by most operators. Conversely if a routine approach to episiotomy use was the operator's usual approach at OVD then employing a restrictive approach was challenging. These findings were supported by the data from the feasibility study which suggested that factors influencing whether or not the woman was randomised included the perceived difficulty of the delivery and the grade of operator. Randomisation was less likely in complex deliveries and if the operator was inexperienced. Fetal distress appeared to be a barrier to randomisation however the woman whose OVD was indicated for fetal distress and was randomised had a decision to delivery time of 18 minutes which suggests that the urgency of delivery would have precluded randomisation in few cases.

Potential participants were not recognised as such when the decision was made to deliver them by OVD which led to a failure to randomise. A limitation of the study was that it did not investigate the barriers to randomisation systematically. Anecdotal evidence however suggested operators may have often been unaware of a women's consent having been provided for randomisation in the trial if OVD was recommended.

Strategies were developed to inform the design of the proposed pilot RCT in an attempt to mitigate the identified limitations in the feasibility study design. Improved flagging of the participants' hand held maternity record was proposed to highlight that the women's consent to participate in the trial had been received. An effort was made to "brand" the

trial with the addition of an easily recognisable graphic which was included alongside the University of Dundee logo to form a headed paper on which all trial paperwork was printed. The design of a visually attractive sticker including this graphic, which was placed in appropriate areas of the women' notes, was key to improved visibility of women who had consented to participate in the trial (Appendix 20). A copy of the written consent form, on the trial headed paper, was also filed in the women's hand held notes in line with the ICH Tripartite Guidelines for Good Clinical Practice.

An oral request to participants was proposed (made by the individual obtaining written consent) to remind obstetric staff discussing OVD in the second stage of labour of their wish to take part in the trial.

Improved peer education was thought necessary regarding the trial which included the placement of a randomisation instruction sheet in the participants hand held maternity record in addition to the instruction sheet displayed next to all computers in labour suite likely to be used for randomisation purposes.

A letter of thanks to the delivering obstetrician for randomising the participant was sent from the study's chief investigator and the author (Appendix 21). Alternatively a letter was sent reminding the operator of the study protocol if a protocol violation occurred (Appendix 22). In addition regular distribution of newsletters (EPIStle) informed staff of the progress of the trial (Appendix 23).

Lastly the use of a notice on the delivery room door announced the occupant's wish to participate in the trial (Appendix 24).

2. To assess acceptability of such a study to participants and operators

A high rate of recruitment was achieved in those approached to consider participation in the study with no loss to follow-up, reflecting the acceptability to women of participating in such a trial.

Recruitment achieved a study population that was representative of the wider pregnant population with regard to the need for OVD. The rate of operative delivery for this cohort (17%) is comparable with reported rates both locally, 14% in 2003 (unpublished local maternity statistics) and nationally, 12.5% in 1999 (National Sentinel Audit, 2001; Births in Scotland report, NHS Scotland 2003).

A further measure of acceptability of trial participation was the positive response (67%) to the question posed at the six week follow-up: "if given the choice would you participate in this study again?"

The assessment of study acceptability to healthcare professionals responsible for aspects of the conduct of the study is crucial to the success of any future pilot study. Two main problem areas were identified during this feasibility study, which warrant further attention – participant recruitment and randomisation of eligible participants as already discussed.

The numbers of women recruited to participate in the trial were less than anticipated. The rate of the uptake to invitation was high indicating the problem lay not with acceptability of the study to women but more with the numbers of women approached to participate.

Problems were encountered with recruitment by community midwives resulting in fewer numbers than had been hoped for in the initial trial proposal. Discussion by the author to gain a more in depth exploration of difficulties experienced by community midwives regarding recruitment to the feasibility study highlighted that the recruitment period had coincided with the introduction of a midwife led facility for low risk women in labour which community midwives were understandably very keen to promote. This led to reluctance on

the part of some midwives to approach women to discuss a study concentrating on OVD as there is some evidence to suggest that emphasising the "normal" tends to improve labour outcomes in terms of mode of delivery (Feldman and Hurst 2007). It was also a period of considerable change in other aspects of care provision, which midwives at times struggled to cope with. Although this situation was identified early in the recruitment period and efforts were made to mitigate the situation by support provided by the author this remained a limitation in the study design throughout the recruitment period

A limitation of this work is that the assessment of acceptability of the study to operators was not investigated more independently. Any discussion with operators was with a member of the study team and it could be that barriers existed which were not verbalised in an attempt to avoid offence. An additional measure which may have been helpful would have been to undertake a short anonymous exit questionnaire and/or interview conducted by an independent researcher. Either of these methodologies might have afforded us a greater understanding of the barriers felt by practitioners and better equipped us to address them and would have allowed us to elicit individual's views on the study design and the importance of the study question.

Strategies were developed to attempt to mitigate the identified limitations in the feasibility study design will which inform the design of the proposed pilot RCT. A more targeted approach is proposed to recruitment, concentrating efforts on women at known higher risk of OVD, specifically primiparae and those admitted to hospital prior to induction of labour. Logistically all women cannot be approached for consideration of trial participation therefore it seems a good use of human resources to concentrate on those groups in which the incidence of the studied procedure is higher. Justification for a trial inclusion criteria based on parity is founded on evidence from currently published statistics (Births in Scotland report, NHS Scotland 2003), supported by a summary of Tayside Obstetric

Activity, 2004 indicating that 72% of all attempted OVD in Ninewells Hospital are undertaken in nulliparous women. There is also some evidence from the literature that the primary and secondary outcome measures under examination are more associated with primiparity than multiparity (Williams 2003). This position is further justified by data from the feasibility study in which all women randomised were nulliparous despite 23% of those eligible for randomisation being multiparous. From these results, in conjunction with a more restrictive use of episiotomy in multiparous women being reported in the national survey of practice as discussed in chapter two of this thesis, it would seem plausible to surmise that operators would be more comfortable with conducting this RCT only in primiparae.

To encourage recruitment to the trial of interested women by community midwives there would be an increased emphasis placed on staff training and support. Continuing education will be provided to nurture enthusiasm for research and empower midwives to recruit to the trial. The name of the community midwife who is highest monthly recruiter will be published in the proposed newsletter and she will also receive a token of gratitude from the research team for her efforts.

3. To inform a sample size calculation for the proposed pilot RCT of routine versus restrictive use of episiotomy at OVD

The lower than expected number of study participants recruited to the study resulted from less than hoped for recruitment in the community setting and an underestimation of the number of women available for approach with fewer women than expected attending hospital based antenatal clinics. In addition the actual numbers of OVD over the feasibility study period (n=191) in Ninewells Hospital was lower than expected (based on previous

local statistics). Recruitment was achieved in 16% of cases. These findings would inform the sample size calculation for a larger two centred pilot study.

In conclusion, the aims of this feasibility study were to test the study design and its feasibility in practice, develop the necessary data collection tools and assess acceptability of such a trial to women and their care providers. These aims were achieved with useful experience being gained in the limitations of the study design and its acceptability to obstetricians which will inform changes in the design of the future pilot RCT.

Chapter 4 - A Prospective Cohort Study Of Maternal And Neonatal Morbidity In Relation To Use Of Episiotomy At Operative Vaginal Delivery

4.1 Introduction

The national postal questionnaire survey of practitioners, as described in chapter two helped us establish the current variation in choice of instrument and approach to episiotomy use by obstetricians at OVD in the UK and Ireland. A routine use of episiotomy was the reported preferred approach for forceps delivery whilst at vacuum extraction a restrictive approach to episiotomy use was prevalent. This variation in practice is based on *a priori* views held by the majority of obstetricians that episiotomy reduces the risk of extensive perineal tearing at forceps delivery but there is much less certainty in the obstetrician's mind about the relationship between episiotomy use and perineal injury at vacuum extraction.

The literature presents little evidence on which these views can be grounded. To address this paucity of evidence it was proposed to conduct a pilot RCT of routine versus restrictive use of episiotomy at OVD. Although the ideal method of evaluation of an intervention such as episiotomy is an RCT which by design would have internal validity (it would measure what it set out to measure), a drawback of such a study design is it's degree of external validity (the extent to which it can be generalised to the broader pregnant population). In addition there is an element of judgement in the obstetrician's decision whether or not to perform an episiotomy that may not be accurately reflected by the randomisation process. A pilot RCT of this type would be challenging given the ethical difficulties and feasibility issues of recruitment to a study of emergency delivery in the second stage of labour.

To address some of these concerns it was planned to perform a prospective cohort study contemporaneous with the planned pilot RCT. It was considered vital to the interpretation of the pilot RCT findings to establish what was happening to the entire cohort of women undergoing OVD over this time scale in the two study centres. The cohort study would allow us to identify any differences in the pilot RCT study population from the broader community undergoing this intervention.

The objective of this study was to establish the maternal and neonatal morbidity associated with episiotomy use at OVD as compared to women who did not receive an episiotomy at OVD within an entire cohort of nulliparous women delivered by forceps or vacuum extraction over the period of the planned pilot RCT and to demonstrate generalisability of the pilot RCT findings.

4.2 Methods

4.2.1 Setting

Ninewells Hospital, Dundee and St. Michael's Hospital, Bristol are consultant led maternity units in teaching hospitals with approximately 3500 and 4700 deliveries respectively in 2005 and OVD rates of 14.5% and 11% respectively. These units differ in their instrument preference with clinicians in Dundee favouring forceps delivery (79.6% forceps vs 20.4% vacuum) and those in Bristol preferring vacuum extraction (51.5% vacuum vs 48.5% forceps), reflecting national variation in practice. There are labour ward protocols in each unit that provide guidance on the conduct of OVD but the approach to use of episiotomy is left to the individual obstetrician or supervising obstetrician according to experience.

4.2.2 Population descriptive variables

Excepting those who had been randomised within the ongoing pilot RCT, all women delivered by OVD in these units were eligible for inclusion in the study if they met the same eligibility criteria as those applied to the pilot RCT i.e. nulliparous (no previous delivery ≥ 24 weeks gestation), with a live singleton pregnancy and cephalic presentation at term (gestation of ≥ 37 weeks). Those women who had consented to participate in the pilot RCT and despite being delivered by forceps or vacuum were not randomised were included in this prospective cohort study. This methodology was adopted to facilitate a like for like comparison between the two study populations. Participants were identified from labour ward records and the electronic maternity databases in each study centre. The study period in Dundee was from October 2004 to September 2006 and in Bristol from June 2005 to August 2006.

4.2.3 Exposures

A dataset was completed from hand written records and the computerised obstetric and neonatal databases (Appendix 25). Detailed data were extracted on maternal and infant characteristics, antenatal, intrapartum and postnatal factors and the outcome measures of interest. Body mass index (BMI) was measured as booking weight (kg) / height $(m)^2$. Small for gestational age (SGA) was defined as a birth weight less than the tenth centile using a customised weight centile calculator (birth weight corrected for maternal height and weight, parity, infant sex, ethnicity and gestation) (Gardosi and Francis 2009). Total duration of labour included both the first and second stages of labour and was classified as prolonged if it exceeded 12 hours. The second stage of labour included the passive and active phases and was considered prolonged if more than two hours duration. A CTG showing persistent late decelerations, tachycardia (>160 bpm) with decelerations or

bradycardia for more than ten minutes in the second stage of labour was considered pathological. Fetal malposition was defined as OT or OP position.

4.2.4 Outcome measures

The primary outcome measure was tearing involving the anal sphincter (third or fourth degree tears). Secondary outcomes were PPH, shoulder dystocia, analgesia requirements, the length of postnatal hospital stay, urinary or bowel symptoms, and the rate of healing complications. Neonatal outcomes included low Apgar scores, low arterial blood gases, admission to NICU and trauma.

Classification of anal sphincter tears was those described in chapter one (Sultan 1999). Estimated blood loss was a global estimate as routine weighing of swabs etc was not performed. Primary PPH was defined as an estimated blood loss at delivery and in the first 24 hours of more than 500mls. Use of a urinary catheter beyond 24 hours was regarded as prolonged. Moderate or strong analgesia was defined as any analgesia excluding paracetamol (usually non-steroidal anti-inflammatory drugs or opioids) in the inpatient period or as an outpatient up to the tenth postnatal day. Postnatal stay was considered prolonged if more than three days' duration. Neonatal resuscitation included intermittent positive pressure ventilation (IPPV) by bag and mask or intubation and cardiac massage but excluded facial oxygen or oropharyngeal suction. Neonatal trauma included bruising, laceration, cephalhaematoma, retinal haemorrhage, facial nerve palsy, BPI and fractures. Serious neonatal trauma was defined as neonatal trauma excluding cases of bruising and skin abrasions. Umbilical arterial and venous samples were routinely taken to measure levels of blood gases (oxygen and carbon dioxide), pH and base deficit. Arterial pH, less than 7.10, and base deficit, greater than 12.0 mmol/l, were used as the thresholds to

define significant fetal acidosis. Maternal and neonatal complications were defined clinically by the attending clinicians.

4.2.5 Statistical analysis

Descriptive statistics of the maternal, neonatal, labour and delivery factors were used to characterise the cohort in relation to use of episiotomy. The primary analyses were a comparison between those who received an episiotomy versus no episiotomy use for both primary and secondary outcomes. Results are presented as OR and 95% CI or with Chi-square tests for differences in proportions and student t test for differences in means. Multivariable logistic regression models were performed adjusting for important confounding factors. Factors tested in the multivariable models were based on a statistically significant difference between the two groups in the univariable analyses ($p<0.05$) or if there was a biologically plausible potential for confounding. Results are reported as adjusted OR with 95% CI. Sub-group analyses compared the primary and secondary outcomes according to use of vacuum or forceps for delivery. The statistical package SPSS (version 13.0) was used for analysis.

4.2.6 Funding and ethical approval

Funding for this study was provided by Tenovus (Scotland) (T03/23) and a favourable ethical opinion of the research was given by the Medical Research Ethics Committee for Scotland A (REC reference number: 04/MRE10/29). The University of Dundee agreed to act as sponsor for the study.

4.3 Results

4.3.1 Characteristics of the cohort in relation to episiotomy use

Over the study period 1360 women having had an OVD in the second stage of labour were included in this cohort study; 1243 who had not been recruited to the contemporaneous RCT and 117 who had been recruited but were not randomised. An episiotomy was performed on 1066 (78.4%) women. Factors significantly associated with use of episiotomy included maternal pre-eclampsia OR 2.23 (95% CI 1.01 to 4.95) increasing infant birth weight (p=<0.001) and head circumference (p=0.001), spinal anaesthesia OR 2.35 (95% CI 1.50 to 3.68), prolonged total duration of labour OR 2.39 (95% CI 1.72 to 3.31), prolonged second stage of labour OR 1.82 (95% CI 1.41 to 2.37), meconium stained liquor OR 1.42 (95% CI 1.07 to 2.00) and fetal malposition OR 2.38 (95% CI 1.75 to 3.24) (Tables 4.1, 4.2). Vacuum delivery was associated with significantly less use of episiotomy than forceps OR 0.16 (95% CI 0.12 to 0.22) as was birth of a SGA infant OR 0.67 (95% CI 0.47 to 0.96), use of pudendal anaesthesia OR 0.62 (95% CI 0.44 to 0.87) and a pathological CTG recording OR 0.62 (95% CI 0.48 to 0.80). These factors were all identified as possible confounders to the primary and secondary outcomes and as such were tested in the multivariable models. Operator grade did not appear to significantly influence the use of episiotomy.

Table 4.1 Maternal and neonatal characteristics in relation to use of episiotomy at OVD

	Episiotomy n=1066	No Episiotomy n=294	OR (95% CI) p = [i]
Maternal Age >35 years (%)	87(8.2)	22(7.5)	1.10(0.67 – 1.78)
Body mass index >30 [ii] (%)	107(10.4)	20(6.9)	1.49(0.91 – 2.42)
Pre-eclampsia (%)	55(5.2)	7(2.4)	2.23(1.01 – 4.95)*
Suspected IUGR [iii] (%)	23(2.2)	11(3.7)	0.57(0.27 – 1.18)
Induction of labour (%)	353(33.1)	94(32.0)	1.06(0.80 – 1.39)
Small for gestational age [iv] (%)	132(13.0)	52(18.2)	0.67(0.47 – 0.96)*
Gender male (%)	575(54.6)	154(52.7)	1.08(0.83 – 1.40)
Gestational age (wks + days) Mean(SD(days)) [range]	40^{+2}(8) [37 – 43^{+4}]	40^{+2}(9) [37 – 42^{+4}]	1(0 – 2) p=0.13
Birth weight(g) Mean(SD) [range]	3481(447) [1870 – 5180]	3375(481) [1960 – 4830]	106(47 – 164) p=<0.001
Head circumference(cm) Mean(SD) [range]	35.0(1.2) [30.5 – 39.9]	34.7(1.3) [30.5 – 38.0]	0.3(0.1 – 0.4) p=0.001

i student t test for differences in means,

ii BMI measured as booking weight/height 2 (kg/m2).Numbers and denominators refer to women where height and booking weight were recorded.

iii Intra uterine growth restriction (IUGR)

iv Small for gestational age baby based on calculated birth weight <10th percentile

* significant, p <0.05

Table 4.2 Labour and delivery factors in relation to use of episiotomy at OVD

	Episiotomy n=1066	No Episiotomy n=294	OR (95% CI)
Opioid analgesia (%)	32(3.0)	15(5.1)	0.57 (0.30 - 1.08)
Epidural analgesia (%)	636(59.7)	170(57.8)	1.00§
Pudendal block (%)	130(12.2)	56(18.9)	0.62 (0.44 - 0.87)*
Spinal anaesthesia (%)	220(20.6)	25(8.4)	2.35 (1.50 - 3.68)*
Labour duration [i] > 12 hours (%)	354(33.4)	51(17.3)	2.39 (1.72 - 3.31)*
Second stage duration [ii] >2 hours (%)	680(64.0)	145(49.3)	1.82 (1.41 - 2.37)*
Pathological CTG [iii] (%)	504(47.3)	174(59.2)	0.62 (0.48 - 0.80)*
Meconium stained liquor (%)	292(27.5)	60(20.6)	1.46 (1.07 -2.00)*
Fetal malposition [iv] (%)	412(38.8)	61(21.0)	2.38 (1.75 - 3.24)*
Vacuum delivery (%)	256(24.0)	200(68.0)	0.16 (0.12 -0.22)*
Forceps delivery (non-rotational) (%)	655(61.4)	82(27.9)	1.00§
Forceps delivery (rotational) (%)	155(14.5)	12(4.1)	1.62 (0.86 - 3.04)
Operator SHO (%)	171(16.1)	59(20.2)	0.86 (0.61 - 1.22)
Operator SpR Year 1-3 (%)	545(51.2)	162(55.5)	1.00§
Operator SpR Year 4-5+ (%)	263(24.7)	53(18.2)	1.42 (0.83 - 2.43)
Operator Consultant (%)	86(8.1)	18(6.2)	1.34 (0.79 - 2.26)
Number of pulls > 3 (%)	66(6.6)	12(4.3)	1.56 (0.83 - 2.93)
Use of sequential instruments (%)	117(11.0)	21(7.1)	1.60 (0.99 -2.60)

§ Category assigned as reference for comparison

* significant, p <0.05

i Labour duration included first and second stage of labour.

ii Included the passive and active phases of second stage of labour.

iii Cardiotocograph (CTG) showing persistent late decelerations, tachycardia (>160 bpm) with decelerations, bradycardia (<100 bpm) for >10minutes in second stage.

iv Occipto transverse and Occipito posterior positions of the fetal head.

4.3.2 Primary and secondary analyses

4.3.2.1 Maternal

An intact perineum was achieved in 44 of the 294 (15%) deliveries performed without an episiotomy (Table 4.3). Lacerations varied from minor abrasions to extensive perineal tears in both groups. Anal sphincter tears were not significantly more likely with the use of episiotomy than without, even after adjusting for possible confounders [adjusted OR 1.11, (95% CI 0.66 to 1.87)]. Episiotomy use was associated with a significantly greater risk of primary PPH [adjusted OR 1.72, (95% CI 1.21 to 2.45)], prolonged use of a urinary catheter [adjusted OR 1.87, (95% CI 1.01 to 3.46)], use of moderate or strong analgesia [adjusted OR 3.70, (95% CI 2.60 to 5.27)] and [adjusted OR 3.35, (95% CI 2.49 to 4.51)] for inpatient and out patient respectively, prolonged postnatal stay [adjusted OR 1.47, (95% CI 1.01 to 2.14)], perineal infection [adjusted OR 4.04, (95% CI 1.44 to 11.37)] and antibiotic use up to the tenth postnatal day [adjusted OR 1.47, (95% CI 1.05 to 2.06)]. The risk of shoulder dystocia was not reduced by use of episiotomy [adjusted OR 1.42, (95% CI 0.53 to 3.85)]. Rates of adverse urinary and bowel symptoms were similar with or without episiotomy use.

Table 4.3 Maternal outcomes in relation to use of episiotomy at OVD

	Episiotomy n=1066	No episiotomy n=294	Unadjusted OR (95% CI)	Adjusted OR [i] (95% CI)
Intact perineum (%)		44(15.0)		
Third/Fourth degree tear (%)	106(9.9)	21(7.1)	1.44 (0.88 - 2.34)	1.11(0.66 - 1.87)
Shoulder dystocia (%)	37(3.5)	5(1.7)	2.08 (0.81 - 5.33)	1.42(0.53 - 3.85)
Primary postpartum haemorrhage (%)	303(28.5)	54(18.4)	1.76 (1.28 - 2.44)*	1.72(1.21 - 2.45)*
Urinary catheter > 24 hours (%)	137(12.9)	13(4.4)	3.19 (1.78 - 5.72)*	1.87(1.01 - 3.46)*
Urinary retention (%)	10(0.9)	4(1.4)	0.69 (0.21 - 2.21)	0.42(0.12 -1.49)
Urinary incontinence (%)	40(3.8)	10(3.4)	1.11 (0.55 - 2.24)	0.85(0.41 - 1.77)
Faecal incontinence (%)	10(0.9)	4(1.4)	0.69 (0.21 - 2.21)	0.44(0.13 - 1.51)
Inpatient moderate/strong analgesia use (%)	945(90.5)	196(67.6)	4.58 (3.32 - 6.31)*	3.70(2.60 - 5.27)*
Postnatal admission > 3 days (%)	230(21.6)	42(14.3)	1.66 (1.16 - 2.37)*	1.47(1.01 - 2.14)*
Outpatient moderate/strong analgesia use [ii] (%)	680(66.3)	92(32.1)	4.18 (3.16 - 5.53)*	3.35(2.49 - 4.51)*
Perineal infection [ii] (%)	54(5.1)	4(1.4)	3.87 (1.39 - 10.77)*	4.04(1.44 - 11.37)*
Any antibiotic use [ii] (%)	301(28.2)	58(19.7)	1.60 (1.17 - 2.20)*	1.47(1.05 - 2.06)*

i Adjusted for birth weight, head circumference, long second stage of labour, fetal distress, spinal anaesthesia, fetal malposition

ii Up to the 10th postnatal day

* significant, p <0.05

4.3.2.2 Neonatal

Use of episiotomy was associated with significantly higher rates of overall neonatal trauma [adjusted OR 1.65, (95% CI 1.20 to 2.27)] but the association was no longer statistically significant when bruising and skin abrasions were excluded [adjusted OR 1.44, (95% CI 0.71 to 2.94)]. Episiotomy use did not influence the condition of the baby at birth (low Apgar scores, fetal acidosis) or admission to NICU (Table 4.4).

Table 4.4 Neonatal outcomes in relation to use of episiotomy at OVD

	Episiotomy n=1066	No episiotomy n=294	Unadjusted OR (95% C.I.)	Adjusted OR [i] (95% C.I.)
Neonatal resuscitation [ii] (%)	107(10.1)	34(11.7)	0.85(0.57 to 1.28)	0.72(0.48 - 1.08)
Apgar score at 1 min ≤ 3 (%)	22(2.1)	9(3.1)	0.67(0.30 to 1.46)	0.46(0.20 - 1.06)
Apgar score at 5 min < 7 (%)	11(1.0)	2(0.7)	1.52(0.34 to 6.90)	1.38(0.29 - 6.60)
pH umbilical artery < 7.10 (%)	64(8.2)	16(6.9)	1.20(0.68 to 2.12)	1.11(0.61 - 2.02)
Base excess artery < -12.0 (%)	40(5.3)	8(3.7)	1.49(0.69 to 3.23)	1.23(0.87 - 1.74)
Neonatal trauma [iii] (%)	403(38.1)	64(22.0)	2.17(1.61 to 2.96)*	1.65(1.20 - 2.27)*
Significant trauma [iv] (%)	56(5.3)	10(3.4)	1.57(0.79 to 3.12)	1.44(0.71 - 2.94)
Admission to NICU [v] (%)	88(8.3)	22(7.6)	1.11(0.68 to 1.81)	1.07(0.62 - 1.86)

i Adjusted for birth weight, head circumference, long second stage of labour, pathological CTG, spinal anaesthesia, fetal malposition

ii Excludes oropharyngeal suction and facial oxygen

iii Includes bruising, skin abrasions, facial nerve palsy, Erb's palsy, fractures, retinal haemorrhage and cephalhaematoma

iv Neonatal trauma excluding bruising and skin abrasions

* significant, $p < 0.05$

4.3.2.3 Subgroup analyses

Vacuum delivery was performed in 456 (33.5%) cases and forceps delivery in 904 (66.5%) cases (Table 4.5). Episiotomy was performed in 256 (56.1%) vacuum deliveries and 810 (89.4%) forceps deliveries. An intact perineum was achieved in 34 of 200 (17%) vacuum deliveries performed without an episiotomy compared to ten of 94 (10.6%) forceps deliveries. Episiotomy was not protective of tears involving the anal sphincter at either vacuum delivery [adjusted OR 0.65, (95% CI 0.26 to 1.66)] or forceps delivery [adjusted OR 0.97, (95% CI 0.48 to 1.95)]. The rate of anal sphincter tearing at forceps delivery was approximately twice the rate at vacuum extraction. The risk of primary PPH remained significantly higher for vacuum delivery completed with an episiotomy [adjusted OR 1.85, (95% CI 1.07 to 3.21)] but not for forceps delivery [adjusted OR 1.09, (95% CI 0.66 to 1.79)]. Episiotomy was associated with significantly greater use of moderate/strong analgesia at both vacuum and forceps delivery in both the inpatient and outpatient period up until discharge from hospital care at ten days postpartum [at vacuum, adjusted OR 2.13, (95% CI 1.34 to 3.40) inpatient and adjusted OR 1.97, (95% CI 1.27 to 3.06) outpatient; at forceps adjusted OR 4.35, (95% CI 2.42 to 7.82) inpatient and adjusted OR 2.66, (95% CI 1.67 to 4.23) outpatient]. No further differences in maternal morbidity were identified according to instrument used. Similarly there were no significant differences in neonatal morbidity in relation to use of episiotomy and choice of instrument for OVD (Table 4.6).

Table 4.5 Maternal morbidity in relation to use of episiotomy and type of OVD

	Vacuum Delivery n=456			Forceps Delivery n=904		
	Episiotomy n=256	No Episiotomy n=200	Adjusted [1] OR (95% CI)	Episiotomy n=810	No Episiotomy n=94	Adjusted [i] OR (95% CI)
Intact perineum (%)	0(0)	34(17.0)	——	0(0)	10(10.6)	——
3rd / 4th degree tear (%)	11(4.3)	11(5.5)	0.65(0.26 – 1.66)	95(11.7)	10(10.6)	0.97(0.48 – 1.95)
Shoulder dystocia (%)	4(1.6)	2(1.0)	1.13(0.18 – 7.05)	33(4.1)	3(3.2)	1.20(0.34 – 4.21)
Postpartum haemorrhage (%)	56(21.9)	26(13.1)	1.85(1.07 – 3.21)*	247(30.6)	28(29.8)	1.09(0.66 – 1.79)
Urinary catheter > 24 hours (%)	8(3.1)	2(1.0)	2.63(0.52 – 13.42)	129(15.9)	11(11.7)	1.22(0.61 – 2.45)
Urinary retention (%)	2(0.8)	2(1.0)	0.78(0.10 – 6.14)	8(1.0)	2(2.1)	0.30(0.06 – 1.55)
Urinary incontinence (%)	5(2.0)	5(2.5)	0.75(0.21 – 2.72)	35(4.3)	5(5.3)	0.71(0.27 – 1.88)
Faecal incontinence (%)	2(0.8)	0(0)	——	8(1.0)	4(4.3)	0.17(0.05 – 0.65)*
Inpatient moderate/strong analgesia use (%)	201(81.4)	127(64.5)	2.13(1.34 – 3.40)*	744(93.4)	69(74.2)	4.35(2.42 – 7.82)*
Postnatal admission > 3 days (%)	42(16.4)	23(11.5)	1.43(0.79 – 2.57)	188(23.3)	19(20.2)	1.12(0.66 – 1.92)
Outpatient moderate/strong analgesia use (%)	98(40.3)	48(24.4)	1.97(1.27 – 3.06)*	582(74.4)	44(48.9)	2.66(1.67 – 4.23)*
Perineal infection (%)	11(4.3)	3(1.5)	3.30(0.89 – 12.31)	43(5.3)	1(1.1)	5.21(0.70 – 38.61)
Any antibiotic use (%)	49(19.1)	32(16.0)	1.23(0.73 – 2.09)	252(31.1)	26(27.7)	1.10(0.68 – 1.79)

i Adjusted for birth weight, head circumference, long second stage of labour, pathological CTG, spinal anaesthesia, fetal malposition

Table 4.6 Neonatal morbidity in relation to use of episiotomy and type of OVD

	Vacuum Delivery n=456			Forceps Delivery n=906		
	Episiotomy n=256	No Episiotomy n=200	Adjusted OR [i] (95% CI)	Episiotomy n=810	No Episiotomy n=96	Adjusted OR [i] (95% CI)
Neonatal resuscitation (%)	25(9.9)	24(12.1)	0.68(0.37 – 1.27)	82(10.2)	10(10.8)	0.82(0.40 – 1.67)
Apgar at 1 min ≤ 3 (%)	7(2.7)	5(2.5)	0.72(0.21 – 2.45)	15(1.9)	4(4.3)	0.36(0.11 – 1.14)
Apgar at 5 min < 7 (%)	4(1.6)	1(0.5)	2.66(0.29 – 24.84)	7(0.9)	1(1.1)	0.76(0.09 – 6.55)
pH umbilical artery < 7.10 (%)	13(7.1)	9(5.8)	1.42(0.57 – 3.52)	51(8.6)	7(9.2)	0.81(0.34 – 1.89)
Base excess artery < -12.0 (%)	8(4.5)	5(3.4)	1.31(0.41 – 4.23)	32(5.6)	3(4.3)	2.04(0.47 – 8.82)
Neonatal trauma (%)	47(18.5)	22(11.1)	1.50(0.85 – 2.67)	356(44.3)	42(45.2)	0.85(0.55 – 1.34)
Significant trauma (%)	18(7.1)	6(3.0)	1.76(0.65 – 4.73)	38(4.7)	4(4.3)	1.07(0.37 – 3.11)
Admission to NICU (%)	16(6.3)	12(6.1)	1.61(0.47 – 2.87)	72(9.0)	10(10.8)	0.78(0.37 – 1.65)

i Adjusted for birth weight, head circumference, long second stage of labour, pathological CTG, spinal anaesthesia, fetal malposition

4.4 Discussion

4.4.1 Summary of main findings

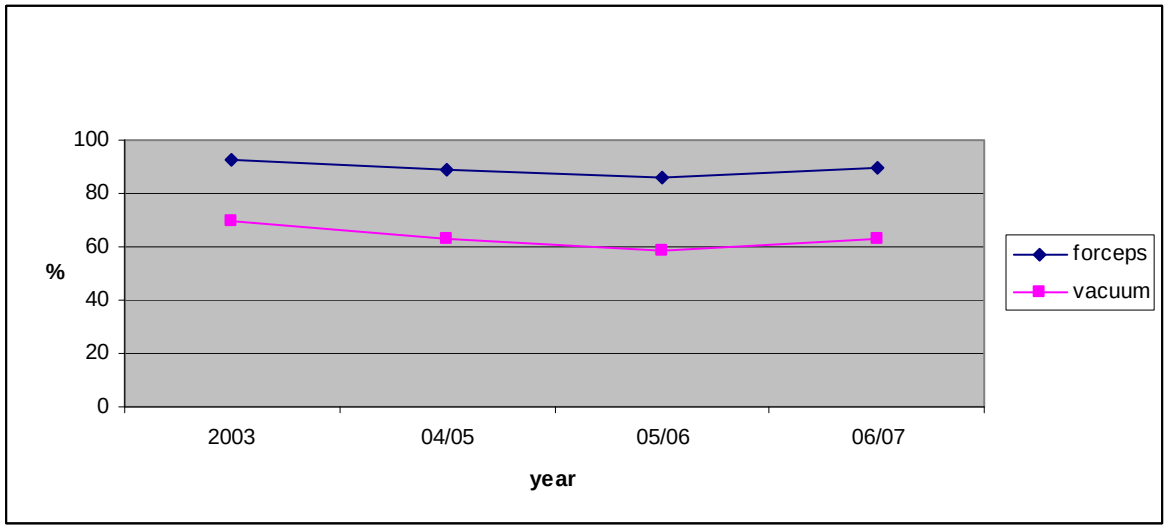
The study found that the use of episiotomy at OVD was not associated with any reduction in the risk of anal sphincter tearing, shoulder dystocia or neonatal trauma as traditionally ascribed to it, however, it was associated with an increased risk of PPH, perineal infection and a greater use of moderate or strong analgesia up to the tenth postnatal day. Rates of adverse urinary and bowel symptoms were similar with or without use of episiotomy although longer term follow-up is required.

4.4.2 Strengths and limitations of the study

The population consisted of a complete geographical cohort of nulliparous women undergoing OVD, in two consultant led units with an obstetric practice typical of that within the UK. Clinicians of all grades of experience performed the deliveries with consultant support available 24 hours a day in accordance with RCOG guidelines. The clinical outcomes were planned prior to data collection and were clear, specific and measurable. They were reported by the attending clinician and there may have been under or over reporting although this potential bias is unlikely to relate specifically to the use of episiotomy. The contemporaneous nature of this study to the pilot RCT has advantages in that results from the study reflect current clinical practice and disadvantages in that there is a potential for bias due to a possible Hawthorne effect. The Hawthorne effect is a well documented phenomenon in which there is a change in a particular human behaviour because it is the focus of study. It is an unavoidable bias in clinical research which must be borne in mind when analysing results of a study. In this instance it may be possible that obstetricians have altered their practice with regard to

episiotomy use due to participation in the pilot RCT. From local unpublished statistics there is evidence of a slight fall in the episiotomy rate at OVD over the study period with an increase in the use of episiotomy following the study period (Figure 4.1). This however is not sufficient to impact on the findings of the prospective cohort study.

Figure 4.1 Episiotomy rate before, during and after the study period by instrument used



The challenge with an observational study lies in the potential for confounding. Women on whom an episiotomy has been performed may be at greater risk of anal sphincter tearing. An attempt has been made to control for this by performing multivariable logistic regression analyses adjusting for relevant factors (factors found to be significantly different in the two study populations or those identified as risk factors for anal sphincter tearing in the literature), however, there may still be residual confounding and the results should be interpreted accordingly.

4.4.3 Comparison with existing literature

The increased risk of anal sphincter tears in association with OVD is well described (Power et al. 2006) although there is conflicting evidence on the role of episiotomy in preventing anal sphincter damage. From the literature reviewed in Chapter one of this thesis established that there are no existing RCTs and a limited number of high quality cohort studies addressing this aspect of intrapartum care. Several studies suggested episiotomy use at OVD may be associated with an increased risk of anal sphincter tears (Combs et al. 1990; Helwig et al. 1993; Kudish et al. 2006; Youssef et al. 2005) while others have shown this association only to be true of fourth degree tears (Ecker et al. 1997; Johnson et al. 2004) or only with one instrument (Robinson et al. 1999– forceps only; Johnson et al. 2004– vacuum only). Other studies have demonstrated a protective role for episiotomy at OVD with regard to anal sphincter tears (Bodner-Adler et al. 2003; de Leeuw et al. 2008). Robinson et al. (1999) found episiotomy use to have no effect on the rate of anal sphincter tears at forceps delivery and Johnson et al. (2004) found episiotomy use to have little effect on the rate of anal sphincter tears at vacuum. The study findings differed from previous studies in that they were consistent both for forceps delivery and vacuum delivery. Neither a protective or deleterious effect of episiotomy use with regard to anal sphincter tearing was detected. This may be due to the prospective design of the study in contrast to the retrospective nature of many of the previous studies.

Maternal and neonatal morbidities were however identified as more prevalent when episiotomy was employed at OVD. A greater risk of primary PPH was found which is consistent with the evidence base supporting a restrictive approach to episiotomy at spontaneous delivery (Carroli and Belizan 1999) and other authors who identified episiotomy use as a risk factor for PPH (Sheiner et al. 2005; Benedetto et al. 2007; Sosa

et al. 2009). Likewise an association between greater analgesic use up to the tenth postpartum day and the use of episiotomy was identified which is consistent with the findings of some previous authors who reported an association between episiotomy use and increased perineal pain (Albers et al. 1999; MacArthur and MacArthur 2004; Declerq et al. 2008; Argentine Episiotomy Trial Collaborative Group 1993) whilst disagreeing with others who found no effect on pain levels (Harrison, 1984; Sleep and Grant 1987). Infection and healing complications were also found to be more likely with episiotomy use which is consistent with the findings of The Argentine Episiotomy Trial Collaborative Group (1993) and Weber and Meyn (2002) although conflicts with the findings of Harrison et al. (1984) who found no such association.

4.4.4 Implications for practice

Given the limitations of observational studies, the most definitive method of assessing the role of episiotomy in preventing or causing anal sphincter tears at OVD delivery remains the RCT. The cohort study supports the selective use of episiotomy at OVD in that significant morbidities were found to be associated with the procedure with no evidence of an increase in anal sphincter tears when the procedure is avoided. However, an RCT of a routine approach to use of episiotomy compared to a restrictive approach would complete the evidence base for obstetricians allowing them to offer women the least traumatic approach when conducting an OVD. This will be discussed in the following chapter.

Chapter 5 - An RCT Of Routine Versus Restrictive Use Of Episiotomy At Operative Vaginal Delivery – A Large Two Centred Pilot Study.

5.1 Introduction

Randomised controlled trials comparing restrictive use of episiotomy with routine use of episiotomy at SVD suggest that there are significant benefits in adopting a restrictive policy, specifically a reduction in posterior perineal tears (Carroli and Belizan 1999). No such evidence base exists for the use of episiotomy at OVD with conflicting evidence from the cohort studies undertaken to date. It is not clear whether episiotomy increases, decreases or has no effect on the rate of third degree tears and there is great variation in the practice of individual obstetricians.

The prospective cohort study as discussed in chapter four of this thesis was conducted contemporaneous to this pilot RCT to take account of concerns raised in the national survey about how generalisable findings of an RCT would be to obstetric practice as a whole. Its findings supported the restrictive use of episiotomy at OVD in that there are significant morbidities associated with the use of episiotomy but no evidence of an increase in anal sphincter tears when the procedure is avoided.

Given the limitations of observational studies, the most definitive method of assessing the relationship between episiotomy and anal sphincter tears at OVD delivery remains the RCT. Therefore, a definitive RCT of a routine approach compared to a restrictive approach to use of episiotomy would complete the evidence base for obstetricians allowing them to offer women the least traumatic approach when conducting an OVD.

The feasibility study (chapter three) conducted in Ninewells Hospital, Dundee demonstrated that it might be possible to undertake such a trial. It afforded the development and testing of assessment tools for follow up questionnaires to elicit

maternal and neonatal morbidities up to six weeks postpartum but shortcomings in the study design were identified, in particular numbers available for recruitment to the study and failure to randomise consented women when delivered by OVD. Whilst these findings have informed changes to the study design of this larger RCT, its limitations would lead to a tempering of ambitions to conduct a definitive trial and in the meantime attempt to conduct a large two centre pilot RCT. With this in mind funding was sought for a study aimed at randomising 200 women over a 12 month period with antenatal and postnatal evaluation of pelvic floor symptoms and assessment of neonatal complications. The study itself may inform future clinical practice if very large differences in the outcomes are detected however it is more likely that smaller differences (if any) will be detected that will inform a future large multi-centre trial.

The objective of this study is to assess the effects of restrictive use of episiotomy compared with routine episiotomy during OVD. The aims are as follows:

- to assess the rate of third/fourth degree tears following restrictive use of episiotomy compared with routine use of episiotomy during forceps and ventouse delivery
- to assess the mother's perception of pain, the length of postnatal hospital stay, and the rate of healing complications following restrictive use of episiotomy compared with routine use of episiotomy
- to assess the rate of neonatal trauma following restrictive use of episiotomy compared with routine use of episiotomy
- to evaluate the feasibility of conducting a definitive multi-centre RCT

- to facilitate sample size/power calculations for the design of a future large multi-centre RCT

5.2 Methods

5.2.1 Participants

The sample comprised nulliparous women at ≥ 37 weeks gestation with a live, singleton, cephalic pregnancy and no contraindication to vaginal delivery. Exclusion criteria included women who were less than 16 years old, women with a limited ability to speak or understand English or other particularly vulnerable groups whom it was thought unethical to approach for consideration of trial participation. Inclusion criteria were limited to nulliparous women based on results of the feasibility study and the literature which identified this group as having a greater likelihood of requiring an OVD and that operators may be more comfortable randomising this group in a trial.

Inclusion criteria in the antenatal period were women who were:

- Age ≥ 16 years
- Nulliparous
- Had a singleton, live pregnancy
- Had no contraindication to randomisation to either arm of the trial on obstetric or medical grounds
- Capable of giving informed consent on an intellectual, ethical or literacy basis

Exclusion criteria in labour were women who:

- had not given written informed consent prior to the onset of labour
- presented with a preterm labour i.e. gestation of < 37 weeks at delivery

- had a non cephalic presentation at delivery
- who were not recommended to have an OVD

5.2.2 Recruitment setting and procedures

A key component of a successful RCT is recruiting a sufficiently large and representative sample to produce robust results which are generalisable to the entire labouring population. In a bid to achieve the aimed for sample size and in view of the limitations to recruitment identified in the feasibility study previously described a decision was made to adopt a two centre approach which would also serve to increase the trials applicability. In addition, a definitive trial would need to recruit large numbers and so would require a multi centred approach to recruitment and so this pilot would inform the feasibility of this strategy.

The maternity unit in Scotland (Ninewells Hospital & Medical School, Dundee) recruited women from October 2004 to September 2006 and the unit in South West England (St Michael's Hospital, Bristol) recruited women from June 2005 to August 2006. Recruitment in England was delayed until contracts were in place and management approval was provided by the Research & Development department. The annual rates of OVD were 14.5% in the Scottish centre and 11% in the English one, which are representative of UK national rates. In the preceding year the Scottish unit had a preference for forceps delivery (80% of OVD) and the English unit similar rates of forceps (51%) and vacuum delivery (49%). An English unit was purposefully chosen as a second centre as it was recognised from maternity statistics that another Scottish centre would have a similar preference for forceps which might not allow us to recruit sufficient numbers being delivered by vacuum extraction to carry out a planned subgroup analysis by instrument. An inability to address this question at vacuum extraction would have implications for the

applicability of the research to current obstetric practice where this mode of delivery is the preferred first instrument of choice of less experienced obstetricians.

Women were recruited in the third trimester, either when attending for antenatal care or when admitted for induction of labour. Ethical approval was not sought to recruit women in labour.

After discussing the trial, women expressing an interest in participation were given an information sheet (Appendix 26), a written consent form (Appendix 27) and a baseline questionnaire on pelvic floor symptoms (Appendix 10). On completion of the forms women were included in the study. A copy of the signed and witnessed consent form was retained by the investigator for the study file, a copy was retained by the participant and the original was placed in the case notes to alert the participant's care team when she was admitted in labour of her wish to participate in the study should she require an OVD. A sticker was also placed in a section in the case notes reserved for "recommendations for labour" which showed the trial logo and confirmed the woman's wish to participate in the trial (Appendix 20). This sticker was developed in response to findings of the feasibility study in which non-identification of participants by the woman's care team in labour was thought to be a contributory factor to the high number of non-randomisations. An instruction sheet of the randomisation process was inserted in each woman's case notes (next to the consent form) and was also posted beside computers in labour suite and in each delivery room to facilitate ease of randomisation as this also was highlighted as a potential problem in the feasibility study (Appendix 28).

5.2.3 Randomisation

Women were randomised to one of two groups if they required an OVD in the second stage of labour. The randomisation was performed, once the decision on mode of delivery

was made, by a web based program using a randomisation sequence generated by a statistician unconnected with the study. Allocation was stratified by maternity unit using randomly permuted blocks of ten.

Due to the need to randomise women 24 hours a day, the participant's hospital number was entered into the program by the attending obstetrician or midwife and the allocation was revealed immediately, prior to the commencement of the OVD. Some randomisations were allocated using sequentially numbered opaque envelopes which were available as back up in case of technical difficulties with the program. The allocation outcome was recorded in the participant's notes. On randomisation the allocation was also generated on a web based allocation log (Appendix 13) which the author cross-checked with the participant's notes to ensure the correct allocation had been assigned.

The author also undertook in-service education with midwives and obstetricians working in the labour suite to familiarise them with the randomisation program. A dummy stratum of the randomisation program was available to allow operators to practise the randomisation process. This was an ongoing exercise throughout the time span of the pilot study.

The participant's GP was notified of their participation in the trial (Appendix 11).

5.2.4 Interventions

Women were allocated to either routine use of episiotomy (in all cases) or restrictive use of episiotomy (only if tearing becomes apparent). Women received usual care for all other aspects of the delivery.

5.2.5 Outcome measures

The primary outcome measure was extensive perineal tearing involving the anal sphincter (third or fourth degree tears). Secondary outcomes included PPH, shoulder dystocia,

perineal pain, the length of postnatal hospital stay, urinary or bowel symptoms and the rate of healing complications. Neonatal outcomes included low Apgar scores, low arterial blood gases, admission to NICU and trauma.

5.2.6 Collection of follow-up data

Clinical follow-up of mother and baby was completed prior to hospital discharge. Data addressing morbidity up to ten days postnatally are presented in this chapter in keeping with the duration of follow-up in the contemporaneous cohort study. Data describing morbidity after this time frame to one year postpartum are presented and discussed in chapter 6.

5.2.7 Sample size

It was estimated that there would be approximately 720 operative vaginal deliveries in primiparae over a one year period across both study centres. In the feasibility study the recruitment rate achieved was only 16% of all women undergoing an OVD. With funding secured for a 12 month recruitment period in each centre, by targeting women at a greater likelihood of requiring this type of delivery i.e. primiparae and women admitted for induction of labour, it was aimed to randomise 200 women (28%).

A previous retrospective cohort study from the Scottish unit (Youssef et al. 2005) suggested a 7.5% rate of anal sphincter tears with OVD using episiotomy and 2.5% where episiotomy was avoided. The two centre pilot RCT data might therefore detect an OR 3.0 comparing third degree tear rates for routine (7.5%) versus restricted (2.5%) use of episiotomy but the results would not be statistically significant unless the sample size was doubled (400 participants in total). Smaller differences than this would be clinically important. Therefore this trial was viewed as exploratory allowing informed estimates for a

large scale definitive trial or as a first study for potential inclusion in a meta-analysis of similar studies.

5.2.8 Statistical analysis

Data analysis proceeded according to CONSORT guidelines for RCTs (Moher et al. 2001). Descriptive statistics were used to characterise the group of individuals recruited to the trial in relation to those eligible and to investigate comparability of the groups at baseline. The primary analyses comprised intention-to-treat comparisons between the two groups for both primary and secondary maternal and neonatal outcomes. Results are presented as OR with 95% CI or with Chi-square tests for differences in proportions and student t test for differences in means (p value). Multivariable logistic regression models were performed adjusting for important confounding factors. Factors were tested in the multivariable models based on a statistically significant difference between the two groups in the univariable analyses ($p<0.05$) or if there was a biologically plausible potential for confounding.

Planned subgroup analyses investigated the primary and secondary maternal and neonatal outcomes according to use of vacuum or forceps for delivery. Results are reported as adjusted OR with 95% CI or p values for comparisons of means and 95% CI of differences.

5.2.9 Funding and ethical approval

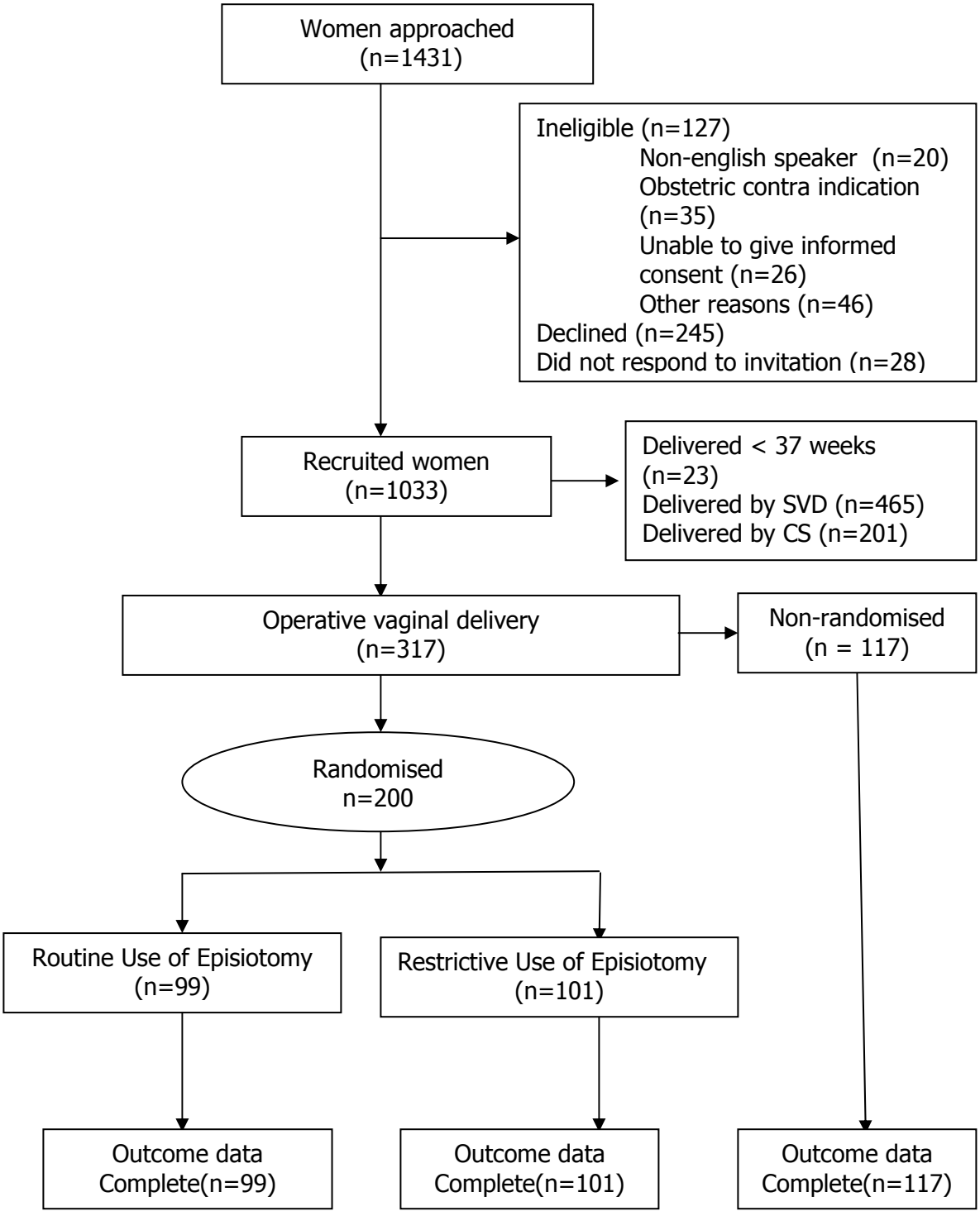
Funding for this study was provided by Tenovus (Scotland) (T03/23). A favourable ethical opinion of the research was given by the Medical Research Ethics Committee for Scotland A (REC reference number: 04/MRE10/29). The University of Dundee agreed to act as sponsor for the study.

5.3 Results

5.3.1 Participants

Of the 1431 antenatal women invited to participate in the trial, 1033(72%) were recruited, 317(31%) required an OVD and of these, 200 were randomised with primary outcome data obtained for all 317 women (figure 5.1). A small number of women delivered spontaneously or by emergency CS although OVD had been the intended method of delivery.

Figure 5.1 CONSORT flowchart



Women who were randomised were more likely than those who were recruited but not randomised to have had labour induced. The babies of women who were randomised were of higher average birth weight than those of women who were not randomised but there were no differences found in head circumference between the two groups (Table 5.1). Women who were randomised were also less likely than those who were recruited but not randomised to have had a long labour or have been delivered by either vacuum extraction or rotational mid cavity forceps (Table 5.2). Otherwise the groups were similar.

Table 5.1 Maternal and neonatal characteristics in relation to randomised versus non randomised individuals at OVD

	Randomised n=200	Non randomised n=117	p=
Maternal Age >35 years (%)	22(11.0)	9(7.7)	0.34
Body mass index >30 [i] (%)	31(15.5)	13(11.1)	0.27
Pre-eclampsia (%)	21(10.5)	7(6.0)	0.17
Suspected IUGR [ii] (%)	7(3.5)	6(5.1)	0.48
Induction of labour (%)	121(60.5)	54(46.2)	0.01*
Small for gestational age (%) [iii]	25(12.5)	18(15.4)	0.48
Gender male (%)	112(56.0)	63(53.8)	0.71
Mean gestational age (wks + days) Mean (SD(days)) [range]	40^{+3} (9) [35^{+6} – 42^{+3}]	40^{+2} (8) [37^{+6} – 41^{+5}]	0.19
Birth weight (g) mean Mean (SD) [range]	3570(508) [2250 – 5060]	3442(431) [2620 – 4580]	0.02*
Head circumference(cm) mean Mean (SD) [range]	35.1(1.3) [31.5 – 38.1]	35.1(1.2) [31.5 – 38.5]	0.99

i BMI measured as booking weight (kg)/height 2 (m).

ii Suspected IUGR – abdominal circumference <10th percentile on ultrasound scan

iii Small for gestational age baby based on calculated birth weight <10th percentile

Table 5.2 Labour and delivery characteristics in relation to randomised versus non randomised use participants at OVD

	Randomised n=200	Non randomised n=117	p=
Opioid analgesia (%)	88(44.0)	62(53.0)	0.12
Epidural analgesia (%)	143(71.5)	85(72.6)	0.83
Pudendal block (%)	27(13.5)	14(12.0)	0.70
Spinal anaesthesia (%)	36(18.0)	16(13.7)	0.32
Labour duration > 12 hours [i] (%)	43(21.5)	43(37.1)	0.003*
Second stage duration >2 hours [ii] (%)	131(65.5)	69(59.0)	0.25
CTG abnormality [iii] (%)	72(36.0)	44(37.6)	0.78
Meconium stained liquor (%)	50(25.0)	22(18.8)	0.20
Fetal malposition [iv] (%)	73(36.5)	49(41.9)	0.34
Vacuum delivery (%)	47(23.5)	33(28.2)	0.047*
Forceps delivery (non-rotational) (%)	116(58.0)	58(49.6)	0.15
Forceps delivery (rotational) (%)	12(6.0)	19(16.2)	0.003*
Spontaneous vaginal delivery (%)	13(6.5)	_____	_____
Caesarean section (%)	12(6.0)	7(6.0)	1.00
Operator SHO (%)	43(22.5)	18(15.4)	0.18
Operator SpR Year 1-3 (%)	112(56.0)	62(53.0)	0.61
Operator SpR Year 4-5+ (%)	31(15.5)	25(21.4)	0.19
Operator Consultant (%)	11(5.5)	12(10.3)	0.12
Number of pulls > 3 (%)	8(4.0)	4(3.5)	0.80
Use of sequential instruments (%)	23(11.5)	15(12.8)	0.73

i Total labour duration included first and second stage of labour.

ii Included the passive and active phases of second stage of labour.

iii Cardiotocograph (CTG) showing persistent late decelerations, tachycardia (>160 bpm) with decelerations, bradycardia (<100 bpm) for >10minutes in second stage.

iv Occipto transverse and OP positions of the fetal head.

Women randomised to routine episiotomy were less likely than women randomised to restrictive use to have been delivered by a senior trainee (SpR Year 4-5+) (10% vs 21%, p=0.037) or CS (5.1% vs 6.9%, p=0.02). No other differences were found between the two groups (Tables 5.3, 5.4).

Table 5.3 Maternal and neonatal characteristics in relation to routine versus restrictive use of episiotomy at OVD

	Routine n=99	Restrictive n=101	p=
Maternal Age >35 years (%)	11(11.1)	11(10.9)	0.96
Body mass index >30 [i] (%)	11(11.3)	20(20.0)	0.10
Pre-eclampsia (%)	9(9.1)	12(11.9)	0.52
Suspected IUGR [ii] (%)	4(4.0)	3(3.0)	0.68
Induction of labour (%)	56(56.6)	65(64.4)	0.26
Small for gestational age (%) [iii]	13(13.4)	12(12.0)	0.77
Gender male (%)	53(53.5)	59(58.4)	0.49
Mean gestational age (wks + days) Mean (SD(days)) [range]	40^{+3} (9) [35^{+6} – 42^{+3}]	40^{+4} (10) [37 – 42^{+1}]	0.88
Birth weight (g) mean Mean (SD) [range]	3589(524) [2250 – 4700]	3550(501) [2510 – 5060]	0.60
Head circumference(cm) mean Mean (SD) [range]	35.1(1.3) [31.5 – 37.8]	35.2(1.2) [31.9 – 38.1]	0.67

i BMI measured as booking weight (kg)/height 2 (m)

ii Suspected IUGR – abdominal circumference <10th percentile on ultrasound scan

iii Small for gestational age baby based on calculated birth weight <10th percentile

Table 5.4 Labour and delivery characteristics in relation to routine versus restrictive use at OVD

	Routine n=99	Restrictive n=101	p=
Opioid analgesia (%)	43(43.4)	45(44.6)	0.87
Epidural analgesia (%)	69(69.7)	74(73.3)	0.58
Pudendal block (%)	17(17.2)	10(9.9)	0.13
Spinal anaesthesia (%)	18(18.2)	18(17.8)	0.95
Labour duration > 12 hours [i] (%)	17(17.2)	26(25.7)	0.14
Second stage duration >2 hours [ii] (%)	64(64.6)	67(66.3)	0.80
CTG abnormality [iii] (%)	39(39.4)	33(32.7)	0.33
Meconium stained liquor (%)	29(29.6)	21(20.8)	0.15
Fetal malposition [iv] (%)	35(35.4)	38(37.6)	0.74
Vacuum delivery (%)	24(24.2)	23(22.8)	0.81
Forceps delivery (non-rotational) (%)	54(54.6)	62(61.4)	0.33
Forceps delivery (rotational) (%)	7(7.1)	5(5.0)	0.53
Spontaneous vaginal delivery (%)	9(9.1)	4(4.0)	_____
Caesarean section (%)	5(5.1)	7(6.9)	0.02*
Operator SHO (%)	23(23.2)	20(19.8)	0.56
Operator SpR Year 1-3 (%)	59(59.6)	53(52.5)	0.31
Operator SpR Year 4-5+ (%)	10(10.1)	21(20.8)	0.037*
Operator Consultant (%)	6(6.1)	5(5.0)	0.73
Number of pulls > 3 (%)	5(5.2)	3(3.1)	0.46

i Total labour duration included first and second stage of labour.

ii Included the passive and active phases of second stage of labour.

iii Cardiotocograph (CTG) showing persistent late decelerations, tachycardia (>160 bpm) with decelerations, bradycardia (<100 bpm) for >10minutes in second stage. iv OT and OP positions of the fetal head.

5.3.2 Primary analyses

There was no statistically significant difference in the incidence of 3°/4° tears on comparing routine with restrictive use of episiotomy at OVD [8.1% vs 10.9%, adjusted OR 0.77, (95% CI 0.28 – 2.10)] (Table 5.5). This finding would suggest that a reduction in the incidence of anal sphincter tears with the adoption of a restrictive approach to episiotomy use at OVD would be unlikely.

5.3.3 Secondary analyses - Maternal outcomes

Routine use of episiotomy was associated with a higher incidence of primary PPH than restrictive use [36% vs 27%; adjusted OR 1.88, (95% CI 0.99 - 3.57)] but rates of shoulder dystocia, urinary complications, faecal incontinence, pain requiring moderate or strong analgesia, prolonged postnatal stay and perineal infection were similar (Table 5.5).

5.3.4 Secondary analyses – Neonatal outcomes

Restrictive use of episiotomy was not associated with adverse neonatal outcomes, in particular, rates of neonatal trauma were similar with slightly more infants sustaining severe trauma in the routine episiotomy group than the restrictive group [9% vs 3%, adjusted OR 3.48 (95% CI 0.85 – 14.26)] (Table 5.6).

Table 5.5 Maternal outcomes in relation to routine versus restrictive use of episiotomy at OVD

	Routine n=99	Restrictive n=101	Unadjusted OR (95% C.I.)	Adjusted OR [i] (95% C.I.)
Episiotomy cut	79(79.8)	47(46.5)	——	——
Intact perineum (%)	1(1.0)	4(4.0)	——	——
Third/Fourth degree tear (%)	8(8.1)	11(10.9)	0.72(0.28 - 1.87)	0.77(0.28 - 2.10)
Shoulder dystocia (%)	8(8.1)	9(8.9)	0.90(0.33 - 2.43)	0.94(0.32 - 2.76)
Primary PPH >500mls (%)	36(36.4)	27(26.7)	1.57(0.86 - 2.86)	1.88(0.99 - 3.57)
Urinary catheter > 24 hours (%)	10(10.1)	11(10.9)	0.92(0.37 -2.27)	0.83(0.33 - 2.10)
Urinary retention [ii] (%)	1(1.0)	1(1.0)	1.02(0.06 - 16.54)	0.71(0.04 - 11.59)
Urinary incontinence [ii] (%)	2(2.0)	4(4.0)	0.50(0.09 - 2.79)	0.46(0.08 - 2.68)
Anal incontinence [ii] (%)	2(2.0)	2(2.0)	1.02(0.14 - 7.39)	1.22(0.15 - 9.79)
Inpatient moderate/strong analgesia use (%)	91(91.9)	90(90.0)	1.26(0.48 - 3.35)	1.20(0.44 - 3.27)
Postnatal admission > 3 days (%)	22(22.2)	20(19.8)	1.16(0.59 - 2.29)	1.22(0.59 - 2.53)
Outpatient moderate/strong analgesia use [ii] (%)	57(57.6)	63(63.6)	0.78(0.44 - 1.37)	0.88(0.49 - 1.59)
Perineal infection [ii] (%)	2(2.0)	1(1.0)	2.06(0.18 - 23.11)	1.88(0.16 - 22.09)
Any antibiotic use [ii] (%)	21(21.2)	28(27.7)	0.70(0.37 - 1.34)	0.90(0.46 - 1.80)

i Adjusted for maternal BMI, prolonged duration of labour (>12 hours), delivery by senior trainee (SpR year 4-5+) ii Up to the 10th postnatal day

Table 5.6 Neonatal outcomes in relation to routine versus restrictive use of episiotomy at OVD

	Routine n=99	Restrictive n=101	Unadjusted OR (95% C.I.)	Adjusted OR [i] (95% C.I.)
Neonatal resuscitation [ii] (%)	13(13.3)	14(13.9)	0.95 (0.42 - 2.14)	1.02(0.44 - 2.36)
Apgar score at 1 min ≤ 3 (%)	4(4.0)	2(2.0)	2.08 (0.37 - 11.65)	1.66(0.29 - 9.53)
Apgar score at 5 min < 7 (%)	2(2.0)	2(2.0)	1.02 (0.14 - 7.39)	0.83(0.11 - 6.16)
pH umbilical artery < 7.10 (%)	4(4.9)	3(4.3)	1.15 (0.25 - 5.30)	0.71(0.14 - 3.74)
Base excess artery < -12.0 (%)	2(2.6)	2(2.9)	0.87 (0.12 - 6.34)	0.77(0.10 - 5.79)
Neonatal trauma [iii] (%)	45(45.5)	44(43.6)	1.08 (0.62 - 1.89)	1.30(0.72 - 2.33)
Severe trauma [iv] (%)	9(9.1)	3(3.0)	3.27 (0.86 - 12.45)	3.48(0.85 - 14.26)
Admission to NICU (%)	6(6.1)	10(9.9)	0.59 (0.21 - 1.68)	0.69(0.23 - 2.08)

i Adjusted for maternal BMI, prolonged duration of labour (>12 hours), delivery by senior trainee (SpR year 4-5+)

ii Excludes oropharyngeal suction and facial oxygen

iii Includes bruising, skin abrasions, facial nerve palsy, Erb's palsy, fractures, retinal haemorrhage, encephalopathy and cephalhaematoma

iv Neonatal trauma excluding bruising and skin abrasions

5.3.5 Subgroup analyses

Fewer women randomised to restrictive use of episiotomy with vacuum delivery received an episiotomy (4/23, 17%) compared to forceps delivery where more than half of those randomised to restrictive use received an episiotomy (43/67, 64%) (Table 5.7). At forceps delivery routine use of episiotomy was not associated with a statistically significant difference in anal sphincter tears compared to restrictive use [9.8% vs 16.4%, (adjusted OR 0.54, 95%CI 0.18 – 1.68)] although there was a modest increase in the incidence of PPH [43% vs 30%, (adjusted OR2.05, 95%CI 0.93 - 4.52)]. At vacuum extraction rates of anal sphincter tears were low but there was a higher incidence of PPH in the routine group compared to the restrictive group [25% vs 4%, (adjusted OR13.44, 95%CI 0.97 - 186.87)]. Urinary, bowel and perineal complications were similar as were neonatal complications irrespective of the approach to use of episiotomy for each type of instrument (Table 5.8).

Table 5.7 Maternal morbidity in relation to routine versus restrictive use of episiotomy and type of OVD

	Vacuum Delivery n=47			Forceps Delivery n=128		
	Routine n=24	Restrictive n=23	Adjusted OR [i] (95% CI)	Routine n=61	Restrictive n=67	Adjusted OR [i] (95% CI)
Episiotomy cut (%)	21(87.5)	4(17.4)	——	58(95.1)	43(64.2)	——
Intact perineum (%)	0(0)	2(8.7)	——	1(1.6)	2(3.0)	——
3rd / 4th degree tear (%)	2(8.3)	0(0)	——	6(9.8)	11(16.4)	0.54(0.18 – 1.68)
Shoulder dystocia (%)	3(12.5)	1(4.3)	5.65(0.37 - 86.54)	5(8.2)	7(10.4)	0.64(0.17 – 2.46)
PPH >500ml (%)	6(25.0)	1(4.3)	13.44(0.97 - 186.87)	26(42.6)	20(29.9)	2.05(0.93 - 4.52)
Urinary catheter > 24 hours (%)	1(4.2)	2(8.7)	0.42(0.03 - 5.11)	7(11.5)	8(11.9)	0.91(0.30 - 2.78)
Urinary retention (%)	0(0)	1(4.3)	——	1(1.6)	0(0)	——
Urinary incontinence (%)	0(0)	0(0)	——	2(3.3)	4(6.0)	0.45(0.07 - 2.75)
Faecal incontinence (%)	0(0)	0(0)	——	2(3.3)	2(3.0)	1.27(0.15 - 10.53)
Inpatient moderate/strong analgesia use (%)	23(95.8)	19(86.4)	2.44(0.19 - 32.10)	60(98.4)	66(98.5)	1.53(0.09 - 25.55)
Postnatal admission > 3 days (%)	3(12.5)	6(26.1)	0.18(0.02 - 1.41)	15(24.6)	10(14.9)	1.98(0.75 - 5.22)
Outpatient moderate/strong analgesia use (%)	11(45.8)	8(38.1)	1.39(0.38 - 5.04)	37(60.7)	48(71.6)	0.65(0.30 - 1.40)
Perineal infection (%)	0(0)	0(0)	——	2(3.3)	1(1.5)	1.84(0.15 - 22.46)
Any antibiotic use (%)	2(8.3)	2(8.7)	1.34(0.14 - 13.27)	18(29.5)	24(35.8)	1.00(0.45 - 2.21)

i Adjusted for maternal BMI, prolonged duration of labour (>12 hours), delivery by senior trainee (SpR year 4-5+)

Table 5.8 Neonatal morbidity in relation to use routine versus restrictive of episiotomy and type of OVD

	Vacuum Delivery n=47			Forceps Delivery n=128		
	Routine n=24	Restrictive n=23	Adjusted OR [i] (95% CI)	Routine n=61	Restrictive n=67	Adjusted OR [i] (95% CI)
Neonatal resuscitation (%)	4(17.4)	4(16.7)	0.98(0.20 - 4.80)	7(11.5)	9(13.4)	0.84(0.28 - 2.53)
Apgar at 1 min ≤ 3 (%)	0(0)	0(0)	——	2(3.3)	2(3.0)	0.65(0.09 - 4.89)
Apgar at 5 min < 7 (%)	1(4.2)	0(0)	——	0(0)	2(3.0)	——
pH umbilical artery < 7.10 (%)	0(0)	0(0)	——	4(8.2)	2(4.2)	1.15(0.18 - 7.59)
Base excess artery < -12.0 (%)	0(0)	0(0)	——	2(4.2)	1(2.2)	1.67(0.14 - 19.76)
Neonatal trauma (%)	11(45.8)	10(43.5)	1.08(0.31 - 3.82)	31(50.8)	33(49.3)	1.36(0.64 - 2.89)
Significant trauma (%)	3(12.5)	1(4.3)	2.67(0.24 - 29.41)	6(9.8)	2(3.0)	3.25(0.57 - 18.46)
Admission to NICU (%)	2(8.7)	2(8.3)	0.71(0.07 - 6.89)	2(3.3)	7(10.4)	0.29(0.05 - 1.57)

i Adjusted for maternal BMI, prolonged duration of labour (>12 hours), delivery by senior trainee (SpR year 4-5+)

5.4 Discussion

5.4.1 Summary of main findings

This two-centre pilot study demonstrates that the conduct of a robust, definitive RCT, appropriately powered to provide clinicians with clear guidance on the optimal use of episiotomy at OVD, would be possible with either a longer recruitment period or more study centres. It also provides robust data for sample size estimates for such a trial.

While not adequately powered to detect significant differences data would suggest that a restrictive approach to use of episiotomy at OVD does not appear to reduce or greatly increase anal sphincter tears compared to routine use. Routine use of episiotomy is associated with an increase in PPH but perineal and neonatal complications rates are similar. Obstetricians are more liberal in their use of episiotomy at forceps than vacuum delivery and this does not appear to have any adverse consequences in terms of anal sphincter damage, perineal morbidity or neonatal complications.

5.4.2 Strengths and Limitations of the study

Randomisation of those eligible increased from 16% in the feasibility study to 63% in the trial. This to some degree endorsed the changes made to the study design, informed by results of the feasibility study, to minimise the number of non-randomisations among recruited eligible women. Women who were recruited but not randomised were more likely than those who were randomised to have been delivered by either vacuum extraction or rotational mid cavity forceps. This may reflect a hesitance on the part of operators to randomise women who it was planned at the time of deciding on OVD to deliver with an instrument which operators' *a priori* views on episiotomy use are less in equipoise (National survey, chapter 2 of this thesis). To

minimise the bias introduced by including obstetricians with strongly held views on the optimal approach to episiotomy use at OVD or who are unwilling to comply with the randomised allocation of women to one approach or another it may be prudent to consider this as an exclusion criteria in the definitive study.

Further confirmation of the success of adjustments to the study design is demonstrated in the rate of OVD amongst recruited women. This rose from 15% in the feasibility study to 31% in the RCT with targeting of high risk populations (primiparae, induction of labour). Despite this however, there was still a slower than hoped for recruitment rate. A no cost extension to the study period was successfully sought from the funders to allow the study recruitment period to increase from 24 months to 39 months across the two centres to achieve randomisation of 200 women. The necessity for an extended recruitment period could be explained by:

- A move towards high risk women only attending hospital based antenatal care hence reducing the pool of women available for approach by research staff to consider participation in the trial
- A lower than expected recruitment rate in the English centre - 60% of women approached to participate compared to 82% in Scotland.
- A randomisation rate of 68% being achieved of those eligible for randomisation

There was a low loss to follow-up reflecting the importance placed by women on this aspect of intrapartum care.

Whilst the results of the study are of direct clinical relevance to care of patients and the study was comparatively large it was not adequately powered to be definitive. Data did not support the hypothesis that a restrictive approach to use of episiotomy would reduce anal sphincter tears however it may be that restrictive use of episiotomy increases anal sphincter tears, particularly at forceps delivery. While on subgroup analysis there was no statistically significant difference in anal sphincter tears at

forceps delivery (9.8% routine vs 16.4% restrictive, OR 0.56, 95%CI 0.19 – 1.61), if these findings persisted in a definitive trial they could represent a halving of risk with a routine approach to episiotomy use which would be of clinical significance. This would be more in line with the findings of the recent Dutch study (de Leeuw et al. 2008). A definitive trial is urgently required to address this issue. A study of 1800 randomised women in each arm would be required to demonstrate the 2.8% absolute difference seen in this study and that would require recruiting some 12000 women in the antenatal period.

At forceps delivery, the rate of episiotomy in the restrictive arm of this study was 64% compared to 95% in the routine arm. As the majority of women still received an episiotomy this may have limited the chance of finding any differences in the primary and secondary outcomes. An adequately powered sub-group analyses taking account of whether forceps or vacuum or indeed both were used would be vital in a definitive trial if findings were to be relevant for all instrument choices. This would again require a larger sample size.

No evidence was found of a large increase or decrease in anal sphincter tears and the absolute event rate was consistent with reported rates in non-trial settings. A drawback of the study design was its degree of external validity (the extent to which it can be generalised to the broader pregnant population). When obstetricians were surveyed, there was concern raised about the validity of a RCT in evaluating a surgical approach that is not dichotomised into two types of practice but one that is based on clinical judgement. There is some justification for this criticism in that obstetricians vary their approach in response to subtle clinical findings and to mitigate for this potential weakness of the pilot RCT a prospective cohort study was conducted alongside the trial to take account of the full spectrum of clinical practice (described in Chapter 4 of this thesis).

It could be argued that the results from the pilot RCT were biased due to the lack of standardisation of the episiotomy technique employed in that obstetricians exercised judgement regarding the technique they employed when cutting an episiotomy e.g. size, angle, and timing. In defence of the study design adopted the question we were attempting to address was 'Is a restrictive approach to episiotomy use more effective than a routine approach at preventing anal sphincter tears when performed by many different obstetricians with varying techniques as found in practice?' To achieve this, a pragmatic approach to the study design was adopted which involved participants, both clinicians and women, like those for which the approach to episiotomy use was relevant in the real world rather than applying a strict definition of episiotomy which would result in any results of the study only being applicable to those obstetricians who employ the specified technique in normal practice. To address this issue in the design of a definitive study it may be useful to consider standardisation of the episiotomy technique but this would have significant cost implications in terms of pre trial training at multiple sites and may result in the loss of some obstetricians who may not be willing to comply with strict criteria of episiotomy technique. An alternative would be to collect data on the size, angle, and timing of the episiotomies cut to establish if these factors are confounding and allow their inclusion in multivariable regression models.

5.4.3 Comparison with existing literature

The literature reviewed in Chapter 1 of this thesis established there are no existing RCTs and a limited number of high quality cohort studies addressing this aspect of intrapartum care. Several studies suggested episiotomy use at OVD may be associated with an increased risk of anal sphincter tears (Combs et al. 1990; Helwig et al. 1993; Kudish et al. 2006; Youssef et al. 2005) while others have shown this association only to be true of fourth degree tears (Ecker et al. 1997; Johnson et al. 2004) or only with

one instrument (Robinson et al. 1999 – forceps only; Johnson et al. 2004 – vacuum only). Other studies have demonstrated a protective role for episiotomy at OVD with regard to anal sphincter tears (Bodner-Adler et al. 2003; de Leeuw et al. 2008). Robinson et al. (1999) found episiotomy use to have no effect on the rate of anal sphincter tears at forceps delivery and Johnson et al. (2004) found episiotomy use to have little effect on the rate of anal sphincter tears at vacuum. The most striking comparison, however, relates to the findings of the recent Dutch study (de Leeuw et al. 2008) where episiotomy was associated with a dramatic reduction in anal sphincter tears for both vacuum and forceps delivery. This magnitude of association, if confirmed within the pilot RCT, would easily have produced statistically significant results but only small differences were found. This may reflect differences in the conduct of OVD, the technique and timing of episiotomy or the marked difference in reported rates of anal sphincter tears between the different settings. Equally it highlights the limitations of observational studies when evaluating a complex clinical intervention

A greater risk of primary PPH was found which is consistent with the evidence base supporting a restrictive approach to episiotomy at spontaneous delivery (Carroli and Belizan 1999) and other authors who identified episiotomy use as a risk factor for PPH (Sheiner et al. 2005; Benedetto et al. 2007; Sosa et al. 2009).

It was acknowledged that adverse morbidity outcomes may have reflected residual confounding associated with the complexity of the procedures rather than the use of episiotomy *per se.* Although restrictive use of episiotomy compared to routine use of episiotomy has been shown to reduce posterior perineal tearing at spontaneous vaginal birth findings did not support a protective role for restrictive use of episiotomy at OVD.

5.4.4 Implications for practice and future research

In the national survey (chapter two), two thirds of obstetricians held the view that routine episiotomy use decreases the likelihood of anal sphincter tears at forceps

delivery with a divided view for vacuum delivery (45% decreases risk, 42% no difference). Less than ten per cent held the view that episiotomy use increased the risk of anal sphincter tears for either forceps or vacuum extraction.

In the contemporaneous prospective cohort study the use of episiotomy at OVD was associated with an increased risk of PPH, perineal infection, neonatal bruising or laceration and a greater usage of moderate or strong analgesia up to the tenth postnatal day without any compensatory reduction in the risk of extensive perineal tearing or shoulder dystocia

This pilot study does not provide conclusive evidence that a policy of routine episiotomy is better or worse than a restrictive policy. The results are compatible with both clinically significant benefits and harms from routine episiotomy.

There are potential advantages in avoiding use of episiotomy for appropriately selected cases. Most obstetricians are liberal in their use of episiotomy for forceps delivery and more restrictive in their use for vacuum delivery. The trial findings support the current variation in use of episiotomy at OVD, reflecting the need for clinical judgement according to the specific circumstances, maternal preferences and skill of the obstetrician pending the conduct of a definitive RCT.

Chapter 6 – Prospective cohort study of morbidity experienced by women after OVD and follow-up of two centre pilot RCT

6.1 Introduction

Much attention is rightly paid in the literature to pelvic floor morbidity given the considerable impact it has on women's lives. Long-term effects of damage to the pelvic floor can include perineal pain, dyspareunia, incontinence of urine and incontinence of flatus or faeces. These morbidities may have a profound impact on women's recovery in the puerperium, long term health and psychological wellbeing. OVD and extensive perineal tears have long been recognised as major risk factors for subsequent morbidity but little scrutiny has been given to the role that episiotomy plays within that.

As previously discussed (chapter 5) the RCT of routine versus restrictive approach to episiotomy at OVD suggested a restrictive approach to episiotomy at OVD neither appeared to reduce or greatly increase anal sphincter tears. The aims of this chapter of the thesis are two fold:

- to examine the longitudinal data collected prospectively as a component part of this pilot RCT investigating the incidence of pelvic floor morbidities and psychological impact on women's lives up to one year postpartum
- to investigate the impact of different approaches to episiotomy use on these morbidities interpreted in light of the longitudinal data

6.2 Methods

6.2.1 Participants

The cohort comprised 200 nulliparous women recruited antenatally and randomised within the previously described pilot RCT of routine versus restrictive use of episiotomy at OVD (chapter 5) followed up to one year postpartum.

6.2.2 Collection of follow-up data

The questionnaires to capture morbidities at baseline (third trimester), on the first or second postpartum day and at six weeks postpartum remained unchanged from the feasibility study as they were found to be easy to use by participants and missing data was minimal (Appendices 10, 16 and 17 respectively). A questionnaire to be administered at one year was devised utilising the same assessment tools (Appendix 29).

6.2.2.1 Baseline data

Baseline data on urinary and bowel morbidity, dyspareunia and psychological wellbeing were collected by self completed questionnaire in the third trimester, usually at the time of consenting to participation in the RCT.

6.2.2.2 Follow up – first or second postpartum day

Clinical follow-up of the woman was completed prior to hospital discharge by visual inspection of the perineum and administration of a self completed questionnaire investigating perineal pain and psychological wellbeing.

6.2.2.3 Follow up – six weeks postpartum

At six weeks postpartum a postal questionnaire was sent to elicit maternal and neonatal health outcomes during the puerperium. Data were obtained on maternal and infant health since delivery, urinary continence, bowel function, dyspareunia, perineal pain and psychological wellbeing. A reminder letter and enclosed questionnaire were sent after four weeks to non responders.

6.2.2.4 Follow up – one year postpartum

A postal questionnaire with covering letter (Appendix 30) was sent to elicit maternal and infant health outcomes which had persisted at one year postpartum. Data were

obtained on maternal and infant health since delivery, urinary continence, bowel function, dyspareunia, perineal pain and psychological wellbeing. As at the six week time point a reminder letter and replacement questionnaire was sent after four weeks if no response had been received (Appendix 31).

6.2.3 Outcome measures

The urinary outcome measures of interest included urinary urgency and frequency; urge urinary incontinence; stress urinary incontinence and reduced urinary sensation up until one year postpartum. Outcomes measures of AI included anal incontinence of flatus; anal incontinence of liquids and anal incontinence of solids up until one year postpartum. In addition the incidence of dyspareunia, perineal pain and psychological morbidity until one year postpartum was investigated.

6.2.4 Statistical analysis

Descriptive statistics were used to investigate comparability of the respondents at each time point to establish if the smaller number of women returning the questionnaire at later time points were unrepresentative of the study population as a whole.

6.2.4.1 Longitudinal prospective cohort study

The first analyses comprised a longitudinal comparison of urinary, anal and sexual outcomes, perineal pain and psychological morbidity at appropriate time points for the entire cohort of OVDs irrespective of the use of episiotomy.

6.2.4.2 RCT analysis

The second analyses investigated the morbidity outcomes according to the approach to episiotomy use at delivery. Multivariable logistic regression models were performed adjusting for baseline differences in morbidity outcomes.

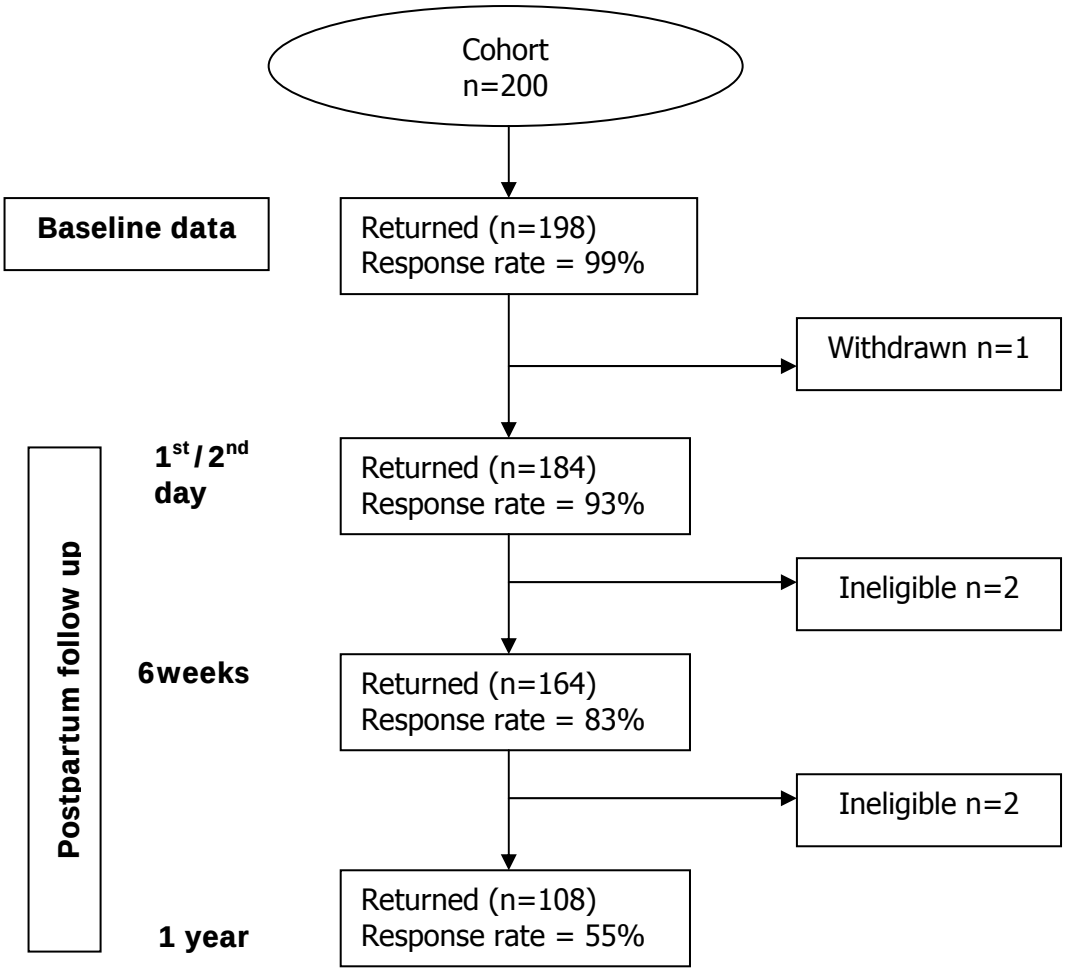
Results are presented with Chi-square tests for differences in proportions and student t test for differences in means (p value).

6.3 Results

6.3.1 Participants prospective cohort study

Baseline data were obtained in the antenatal period from 99% of women who were recruited to and randomised within the RCT. Follow up in the immediate postpartum period was achieved in 93% of cases, 83% of cases at six weeks postpartum, and 55% of cases at one year postpartum (Figure 6.1) Four women became ineligible for the cohort study over the follow up period – in one case it was felt to be inappropriate to contact the mother due to neonatal death (Sudden Infant Death syndrome), the remainder were women who had moved from the area without leaving any forwarding details.

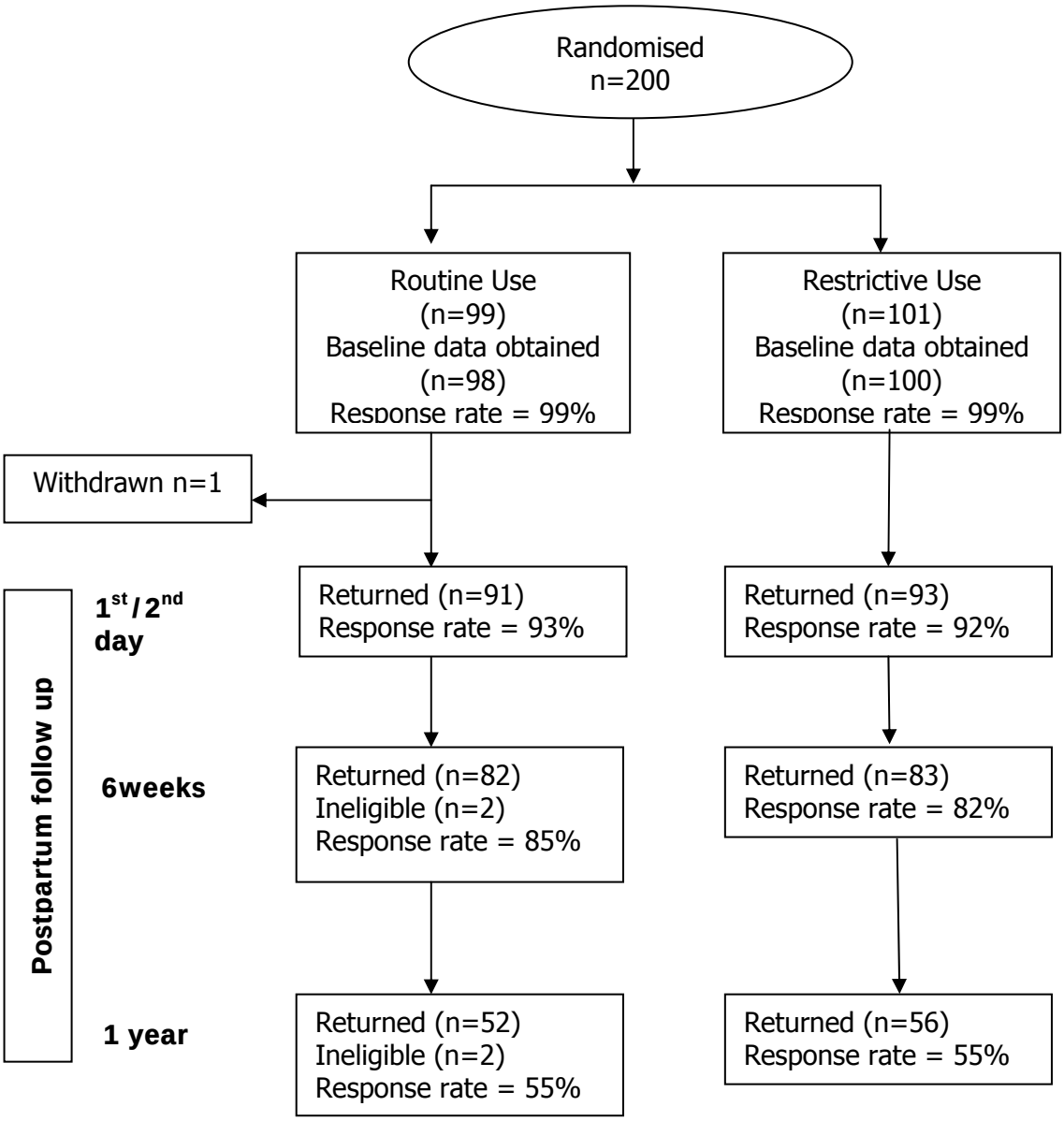
Figure 6.1 Cohort Flowchart



6.3.2 Participants pilot RCT

Baseline data were obtained from 99% of participants randomised to each arm of the pilot RCT. Response rates were balanced between the study arms at all time points (Figure 6.2). All women who withdrew from the study or became ineligible for collection of follow up data (as described earlier) were randomised to the routine arm of the study.

Figure 6.2 CONSORT flowchart



6.3.3 Descriptive statistics

No statistical differences were found in the maternal and neonatal characteristics of respondents between time points (Table 6.1).

Table 6.1 Maternal and neonatal characteristics of cohort respondents

	Antenatal n=198	1st/2nd day postpartum n=184	6 weeks postpartum n=164	1 year postpartum n=108	p=#
Maternal Age >35 years (%)	22(11.1)	21(11.4)	19(11.6)	13(12.0)	0.61
Body mass index >30 [i] (%)	31(15.9)	29(15.9)	28(17.3)	18(17.0)	0.60
Pre-eclampsia (%)	21(10.6)	19(10.3)	17(10.4)	12(11.1)	0.76
Suspected IUGR [ii] (%)	7(3.5)	6(3.3)	6(3.7)	6(5.6)	0.09
Induction of labour (%)	120(60.6)	111(60.3)	104(63.4)	60(55.6)	0.12
Small for gestational age (%) [iii]	25(12.8)	24(13.2)	20(12.3)	14(13.2)	0.81
Gender male (%)	111(56.1)	103(56.0)	88(53.7)	60(55.6)	0.89
Mean gestational age (wks + days) Mean (SD(days))(range)	40^{+3}, 9 ($37– 42^{+1}$)	40^{+3}, 10 (35^{+6} - 42^{+3})	40^{+3}, 10 (35^{+6} - 42^{+3})	40^{+3}, 9 ($37 – 42^{+1}$)	0.66
Birth weight (g) Mean (SD) (range)	3570 (514) [2250–5060]	3563, (513) [2250 – 5060]	3587 (518) [2250 – 5060]	3560, (529) [2250 – 5060]	0.78
Head circumference(cm) Mean (SD) (range)	35.1 (1.3) [31.5–38.1]	35.1 (1.3) [31.5 – 38.1]	35.1 (1.3) [31.5 – 38.1]	35.1 (1.3) [31.5 – 38.1]	0.97

comparison between antenatal and one year postpartum ∗ significant, p<0.05

i BMI measured as booking weight (kg)/height 2 (m) ii Suspected IUGR – abdominal circumference <10th percentile on ultrasound scan

iii Small for gestational age baby based on calculated birth weight <10th percentile.

Respondents at one year postpartum were significantly less likely to have been delivered by an SHO (21.2% vs 14.8%, p=0.01). No other statistically significant differences were found in the labour and delivery characteristics of respondents between time points (Table 6.2).

Table 6.2 Labour and delivery characteristics of cohort respondents

	Antenatal n=198	1st/2nd day postpartum n=184	6 weeks postpartum n=164	1 year postpartum n=108	p=#
Opioid analgesia (%)	7(3.5)	6(3.3)	4(2.4)	2(1.9)	0.17
Epidural analgesia (%)	119(60.1)	111(60.3)	97(59.1)	65(60.2)	0.92
Pudendal block (%)	27(13.6)	24(13.0)	24(14.6)	19(17.6)	0.07
Spinal anaesthesia (%)	35(17.7)	33(17.9)	29(17.7)	16(14.8)	0.28
Labour duration > 12 hours [i] (%)	20(10.1)	18(9.8)	16(9.8)	12(11.1)	0.57
Second stage >2 hours [ii] (%)	130(65.7)	121(65.8)	109(66.5)	73(67.6)	0.50
CTG abnormality [iii] (%)	71(35.9)	67(36.4)	58(35.4)	33(30.6)	0.08
Meconium stained liquor (%)	50(25.4)	46(25.1)	45(27.6)	30(28.0)	0.31
Fetal malposition [iv] (%)	73(36.9)	66(35.9)	56(34.1)	41(38.0)	0.64
Vacuum delivery (%)	47(23.7)	45(24.4)	33(20.1)	20(18.6)	0.07
Forceps delivery (non-rotational) (%)	115(58.1)	106(57.6)	97(59.2)	64(59.3)	0.70
Forceps delivery (rotational) (%)	12(6.1)	11(6.0)	12(7.3)	9(8.3)	0.13
SVD (%)	12(6.1)	11(6.0)	12(7.3)	6(5.6)	0.84
Caesarean section (%)	12(6.1)	11(6.0)	10(6.1)	9(8.3)	0.13
Operator SHO (%)	42(21.2)	43(23.4)	37(22.6)	16(14.8)	0.01*
Operator SpR Year 1-3 (%)	111(56.1)	101(54.9)	87(53.0)	61(56.5)	0.88
Operator SpR Year 4-5+ (%)	31(15.7)	29(15.8)	29(17.7)	21(19.4)	0.10
Operator Consultant (%)	11(5.6)	9(4.9)	9(5.5)	8(7.4)	0.20
Number of pulls > 3 (%)	8(4.1)	8(4.5)	7(4.4)	2(1.9)	0.09
Use of sequential instruments (%)	23(11.6)	21(11.4)	17(10.4)	11(10.2)	0.53

comparison between antenatal and one year postpartum

∗ significant, p<0.05

i Total labour duration included first and second stage of labour.

ii Included the passive and active phases of second stage of labour.

iii Cardiotocograph (CTG) showing persistent late decelerations, tachycardia (>160 bpm) with decelerations, bradycardia (<100 bpm) for >10minutes in second stage

iv Occipto transverse and OP positions of the fetal head.

6.3.4 Longitudinal cohort analyses

Of women who had reported urinary incontinence during pregnancy 66% had persistent urinary incontinence at six weeks postpartum whereas de novo urinary incontinence in the puerperium was reported by 30% of women who had been continent in pregnancy.

Urgency of micturition was reported by 74.7% of women during pregnancy which reduced significantly in the postpartum period to 50.0% ($p<0.001$) of women, with no significant further reduction at one year postpartum (49.5%). Urinary urge incontinence was experienced by up to 37% of women but with no significant differences across the time points examined. Urinary stress incontinence was reported by 41.4% of women in pregnancy but was less prevalent at six weeks postpartum [34.8% ($p=0.24$)] and with a non significant increase at one year postpartum [46.7% ($p=0.07$)]. Reduced urinary sensation was more prevalent in pregnancy than at either six weeks or one year postpartum but differences did not meet statistical significance (13.2% vs 9.8% and 5.7% respectively) (Table 6.3).

Anal incontinence of flatus was more prevalent in pregnancy than the postpartum period, with no significant difference in prevalence at six weeks and one year postpartum [52.5% vs 42.9% ($p=0.09$) and 35.2% respectively ($p=0.25$)]. Anal incontinence of liquids was found to be uncommon but constant across time points, ranging from 4.5 – 6.0%. Anal incontinence of solids was reported by one per cent of women in pregnancy but was a significantly greater problem at six weeks postpartum [4.9% ($p=0.05$)]. This however had resolved in all cases by one year (0%, $p=0.05$).

Moderate or severe dyspareunia was most reported at six weeks postpartum (4.1% antenatal vs 9.6% six weeks postpartum, $p=0.08$) but by one year postpartum the incidence had fallen back to baseline levels [4.7% ($p=0.23$)]. This finding was reflected in the significantly higher levels of dyspareunia having prevented intercourse, reported

by 9.3% of women antenatally, rising to 17.8% (p=0.003) at six weeks postpartum but returning to 9.1% (p=0.03) at one year postpartum.

Table 6.3 Urinary, anal and sexual morbidities up to one year after operative vaginal delivery

	Antenatal n=198	6 weeks postpartum n=164	p=[1]	1 year postpartum n=108	p=[2]
Urgency of micturition (%)	148(74.7)	82(50.0)	<0.001*	52(49.5)	0.94
Urinary urge incontinence (%)	70(35.4)	57(34.8)	0.99	39(37.1)	0.79
Urinary stress incontinence (%)	82(41.4)	57(34.8)	0.24	49(46.7)	0.07
Reduced urinary sensation (%)	26(13.2)	16(9.8)	0.40	6(5.7)	0.34
Anal incontinence of flatus (%)	104(52.5)	70(42.9)	0.09	38(35.2)	0.25
Anal incontinence of liquids (%)	9(4.5)	10(6.1)	0.67	6(5.5)	0.85
Anal incontinence of solids (%)	2(1.0)	8(4.9)	0.05*	0(0)	0.05*
Urgency of defecation (%) [3]	14(7.1)	13(7.9)	0.91	8(7.5)	0.91
Moderate/Severe dyspareunia (%)	8(4.1)	12(9.6)	0.08	5(4.7)	0.23
Dyspareunia preventing intercourse (%)	18(9.3)	29(17.8)	0.003*	9(9.1)	0.03*

∗ significant, p<0.05

1 Comparison of morbidities at baseline and 6 weeks postpartum

2 Comparison of morbidities at 6 weeks postpartum and 1 year postpartum

3 Inability to wait 5 minutes after urge to defecate

All measures of perineal pain were found to reduce significantly with time (Table 6.4). Perineal pain was present for nearly all women in the immediate postpartum period (96.7%) but for less than half of respondents at six weeks (43.9%). For nearly one in five women perineal pain persisted to one year postpartum (17.8%). In addition to affecting a greater number of women immediately after birth the intensity of the pain was found to be more severe on the first or second day than at six weeks postpartum – mean VAS 35 vs 6 respectively; mean McGill pain rating index 11.9 vs 2.0 and mean

McGill present pain intensity score 1.8 vs 0.4. On average, women chose seven words from the McGill questionnaire to describe their pain in the immediate postpartum period compared with only one at six weeks postpartum.

Table 6.4 Perineal pain up to one year after operative vaginal delivery

	1st/2nd day postpartum n=184	6 weeks postpartum n=164	p=[1]	1 year postpartum n=108	p=[1]
Perineal pain present (%)	177(96.7)	72(43.9)	0.07	19(17.8)	0.009*
Perineal pain visual analogue scale (0-100) Mean (SD) [range]	35 (22) [0 – 95]	6 (12) [0 – 75]	<0.001*		
McGill pain questionnaire – pain rating index[2] Mean (SD) [range]	11.9 (10.0) [0 – 44]	2.0 (4.9) [0 – 37]	<0.001*		
McGill pain questionnaire - number words chosen[3] Mean (SD) [range]	7 (5) [0 – 21]	1 (3) [0 – 19]	<0.001*		
McGill pain questionnaire – present pain intensity[4] Mean (SD) [range]	1.8 (0.9) [0 – 5]	0.4 (0.7) [0 – 5]	<0.001*		

* significant, p<0.05

1 Chi squred test for differences in proportions or student t test for differences in means

2 Mean of numerical values assigned to descriptors chosen by participant to specify pain experience (possible range 0 – 79)

3 Mean of number of descriptors chosen by participants to specify pain experience (possible range 0 – 20)

4 Based on a 1 – 5 intensity scale to specify pain experience

The mean EPDS, indicative of possible psychological trauma, was significantly higher in pregnancy than at $1^{st}/2^{nd}$ day postpartum [7.4 vs 5.0, (p<0.001)], remaining constant up to one year postpartum (Table 6.5).

This was reflected in the prevalence of EPDS score $\geq$13, suggestive of clinical depression, which was significantly higher antenatally compared to the $1^{st}/2^{nd}$ day postpartum [14.5% vs 6.5%, (p=0.02)] remaining constant at six weeks postpartum [6.1% (p=0.88)] and one year postpartum [8.4% (p=0.64)].

Table 6.5 Psychological morbidity up to one year after operative vaginal delivery

	Antenatal n=198	1st/2nd day postpartum n=184	p=[1]	6 weeks postpartum n=164	p=[1]	1 year postpartum n=108	p=[1]
Edinburgh Postnatal Depression Score Mean (SD) [range]	7.4 (4.6) [0 – 20]	5.9 (4.2) [0 – 20]	<0.001*	5.0 (4.0) [0 – 16]	0.67	5.4 (5.0) [0 – 22]	0.86
Possible depression (EPDS≥13) (%)	28(14.5)	12(6.5)	0.02*	10(6.1)	0.88	9(8.4)	0.64

* significant, p<0.05 1 chi squared test for differences in proportions or student t test for differences in means

At six weeks postpartum, 100(61%) babies had been seen by their GP or at a hospital clinic. The majority had been seen for minor ailments e.g. infections, rashes but others had been seen due to morbidities which might possibly have been relevant to their delivery - jaundice (n=8), minor trauma secondary to forceps use (n=4) and Erb's palsy/ physiotherapy (n=3). Treatments received by 25 babies included antibiotics (n=13), phototherapy (n=6), assistance with feeding problems (n=4), saline nose drops (n=1), physiotherapy (n=1), surgery (n=1). Ten (6%) babies had been re-admitted to hospital. The method of feeding was reported as breast (35%), bottle (50%) and mixed feeding (15%).

At one year postpartum, 35% of respondents reported their infant had been referred for secondary care since birth. As at six weeks the majority of referrals were for minor ailments or birth defects.

Of respondents who had not reported morbidities at six weeks postpartum or had reported morbidities which were not thought to possibly relate to delivery 37(35%) reported morbidity at one year. Those of possible relevance to delivery included jaundice (n=1), plagiocephaly (n=2), "head held to one side" (n=1), "lump on right eye" (n=1) and visual impairment (n=1). Four infants had been admitted to hospital.

Of infants who had reported a morbidity thought to possibly be relevant to delivery at six weeks postpartum five infants had been referred for secondary care including the two infants with previously reported Erb's palsy and one infant requiring a hearing check. One of the mothers of an infant with Erb's palsy reported it had resolved completely by five months of age. Two infants had been admitted to hospital.

Developmental screenings were attended by 97% of infants. Concerns were raised on four infants only – failure to thrive (n=1), eczema (n=1), developmental delay/visual impairment (n=1), "left eye does not close properly when asleep" (n=1).

6.3.5 Pilot RCT analyses

Postpartum de novo urinary incontinence was reported by 18.9% of women randomised to the routine use of episiotomy compared to 39.5% of women randomised to a restrictive use of episiotomy (p=0.05).

No differences were found between groups for any urinary, anal and sexual morbidity at baseline. No differences were found between groups at either time point postpartum for urgency of micturition, urinary urge incontinence or reduced urinary sensation (Table 6.6). Women complaining of urgency of micturition or urinary urge incontinence postpartum most or all of the time were uncommon (≤ 2%). Urinary stress incontinence was found to be significantly less likely with a routine use of episiotomy than a restrictive use at six weeks postpartum (27.2% vs 42.2% respectively, p=0.03) but this had resolved by one year postpartum (50.0% vs 43.6% respectively, p=0.69). Urinary stress incontinence present "most or all of the time" was reported by 1.2 – 5.5% of women. No statistically significant differences in urinary stress incontinence present "most or all of the time" were found between the groups at either six weeks postpartum (p=0.28) or one year postpartum (p=0.46).

No differences were found between groups for any outcome measure of anal incontinence or dyspareunia at either time point postpartum.

Table 6.6 Urinary, anal and sexual morbidities up to one year after operative vaginal delivery by episiotomy use

	Antenatal			6 weeks postpartum			1 year postpartum		
	Routine n=98	Restrictive n=100	p=[1]	Routine n=81	Restrictive n=83	p=[1, 2]	Routine n=52	Restrictive n=56	p=[1, 2]
Urgency of micturition (%)	78(79.6)	70(70.0)	0.12	39(48.1)	43(51.8)	0.41	26(52.0)	26(47.3)	0.92
Urge incontinence (%)	32(32.7)	38(38.0)	0.43	25(30.9)	32(38.6)	0. 42	21(42.0)	18(32.7)	0.32
Stress incontinence (%)	40(40.8)	42(42.0)	0.87	22(27.2)	35(42.2)	0.03*	25(50.0)	24(43.6)	0.69
Reduced urinary sensation (%)	12(12.2)	14(14.0)	0.69	6(7.4)	10(12.0)	0.36	4(8.0)	2(3.6)	0.35
Incontinence of flatus (%)	57(58.2)	47(47.0)	0.12	37(45.7)	33(40.2)	0.85	18(34.6)	20(35.7)	0.60
Incontinence of liquids (%)	3(3.0)	6(6.0)	0.32	4(4.9)	6(7.2)	0.81	4(7.7)	2(3.6)	0.72
Incontinence of solids (%)	1(1.0)	1(1.0)	0.98	5(6.1)	3(3.6)	0.65	0(0)	0(0)	____
Urgency of defecation (%) [3]	9(9.2)	5(5.0)	0.25	5(6.2)	8(9.6)	0.18	6(11.5)	2(3.7)	0.25
Moderate/Severe dyspareunia (%)	2(2.1)	6(6.1)	0.16	6(7.5)	6(7.2)	0.79	1(1.9)	4(7.1)	0.22
Dyspareunia preventing intercourse (%)	6(6.3)	12(12.2)	0.15	11(13.8)	18(21.7)	0.22	3(6.1)	6(12.0)	0.21

*p<0.05

1 chi squared test for differences in proportion or student t test for differences in means

2 corrected for differences in baseline morbidities

3 Inability to wait 5 minutes after urge to defecate

REEDA was performed on 75% of participants (due to participant's early discharge from hospital prior to physical examination). No differences were found between groups in the mean REEDA score (2.29 vs 2.21, p=0.82).

Perineal pain was significantly less associated with a routine use of episiotomy in the immediate postpartum period (87.8% vs 98.9%, p=0.003) but this difference did not persist at six weeks or one year postpartum. The intensity of pain however at six weeks postpartum, as measured by the McGill questionnaire present pain intensity, was significantly less with a routine approach to episiotomy compared to a restrictive approach (0.3 vs 0.5, p=0.05). Although the differences in other measures of perineal pain (VAS and McGill pain questionnaire - pain rating index and number words chosen) at six weeks postpartum were small and did not meet statistical significance a routine use of episiotomy was consistently associated with less perineal pain than a restrictive use of episiotomy (Table 6.7).

Psychological morbidity was found to be significantly less associated with a routine use of episiotomy compared to a restrictive use in the immediate postpartum period (mean EPDS routine 5.1 vs restrictive 6.7, p=0.01). No differences were found between groups at six weeks (4.4 vs 5.5, p=0.34) and one year postpartum (5.6 vs 5.1, p=0.41). No differences were found in the incidence of an EPDS $\geq$ 13, indicative of possible depression, at either six weeks (3.3% vs 9.7%, p=0.14) or one year postpartum (11.8% vs 5.4%, p=0.16) (Table 6.8). Results were corrected to take account of the differences in baseline levels of psychological morbidity.

Trial acceptability was demonstrated by 90% of women in each group stating they would participate in the trial again if in similar circumstances.

Table 6.7 Perineal morbidity up to one year after operative vaginal delivery by episiotomy use

	1st/2nd day postpartum			6 weeks postpartum			1 year postpartum		
	Routine n=91	Restrictive n=93	p=[1]	Routine n=81	Restrictive n=83	p=[1]	Routine n=52	Restrictive n=56	p=[1]
REEDA[2] Mean (SD) [range]	2.29 (1.99) [0 – 10]	2.21 (1.93) [0 – 9]	0.82						
Perineal pain present (%)	79(87.8)	89(98.9)	0.003*	31(38.3)	34(41.0)	0.73	12(23.1)	7(12.7)	0.16
Perineal pain visual analogue scale (0 – 100) Mean (SD) [range]	32 (23) [0 -95]	37 (21) [0 – 95]	0.10	5 (10) [0 – 45]	7 (14) [0 – 75]	0.21			
McGill pain questionnaire: pain rating index[3] Mean (SD) [range]	11.1 (8.9) [0 – 44]	12.7 (10.9) [1 – 42]	0.27	1.4 (3.4) [0 – 21]	2.6 (6.0) [0 – 37]	0.14			
McGill pain questionnaire: number words chosen[4] Mean (SD) [range]	7 (4) [0 – 20]	7 (5) [1 – 21]	0.33	1 (2) [0 – 13]	2 (3) [0 -19]	0.23			
McGill pain questionnaire: present pain intensity[5] Mean (SD) [range]	1.8 (0.9) [0 – 4]	1.8(0.9) [0 – 5]	0.58	0.3 (0.5) [0 – 2]	0.5 (0.8) [0 – 5]	0.05*			

1 Student t test to compare means or chi squared test for differences in proportions

2 Scoring system to assess perineal redness, oedema, bruising, discharge and alignment following episiotomy or tearing

3 Mean of numerical values assigned to descriptors chosen by participant to specify pain experience (possible range 0 – 79)

4 Mean of number of descriptors chosen by participants to specify pain experience (possible range 0 – 20)

5 Based on a 1 – 5 intensity scale to specify pain experience

Table 6.8 Psychological morbidity up to one year after operative vaginal delivery by episiotomy use

	Antenatal			1st/2nd day postpartum			6 weeks postpartum			1 year postpartum		
	Routine n=98	Restrictive n=100	p=[1]	Routine n=91	Restrictive n=93	p=[1, 2]	Routine n=81	Restrictive n=83	p=[1, 2]	Routine n=52	Restrictive n=56	p=[1, 2]
EPDS Mean (SD) [range]	7.0 (4.3) [0 – 16]	7.8 (5.0) [0 – 20]	0.23	5.1 (3.8) [0 – 16]	6.7 (4.4) [0 – 20]	0.01*	4.4 (3.9) [0 – 16]	5.5 (4.0) [0 – 14]	0.34	5.6 (5.2) [0 – 20]	5.1 (4.8) [0 – 22]	0.41
Possible depression (EPDS≥13) (%)	9(9.3)	19(19.8)	0.04*	9(3.3)	9(9.7)	0.14	5(6.3)	5(6.0)	0.34	6(11.8)	3(5.4)	0.16

*p<0.05

1 chi squared test for differences in proportion or student t test for differences in means

2 corrected for differences in baseline morbidities

6.4 Discussion

The data from the descriptive analysis reassured us that although the response rates at six weeks and one year postpartum was less than at the earlier time points there was no specific population from whom data was missing.

6.4.1 Summary of main findings

6.4.1.1 Longitudinal cohort findings

Postpartum urinary incontinence was reported by up to half of the respondents in this cohort - more prevalent in women who had reported antenatal urinary incontinence but de novo urinary incontinence was reported by one in three women in the postpartum period. Stress urinary incontinence was reported by over one third of respondents at all time points examined. Urgency of micturition was most prevalent in pregnancy and reduced significantly in the puerperium and remained constant at one year postpartum. Anal incontinence of solids was significantly more prevalent at six weeks postpartum than in pregnancy but had resolved in all cases by one year postpartum. Moderate or severe dyspareunia was reported by about five per cent of the cohort antenatally which rose at six weeks postpartum but had fallen back to baseline levels by one year postpartum. As expected perineal pain was found to be present in nearly all women immediately postpartum but resolved over time, still affecting one in five women however to some degree at one year postpartum. Psychological morbidity was found to be most prevalent in pregnancy and significantly less in the immediate postpartum period remaining constant up to one year.

6.4.1.2 RCT findings

Analyses of the RCT reported de novo urinary incontinence to be significantly less associated with a routine approach than a restrictive approach to episiotomy use at OVD. A routine approach to use of episiotomy at OVD does not appear to increase and may even decrease rates of urinary morbidity, in particular stress incontinence, perineal pain and psychological morbidity compared to a restrictive use.

6.4.2 Strengths and Limitations of the study

This longitudinal follow up of participants randomised in a two centred pilot RCT of routine versus restrictive use of episiotomy at OVD provides a comprehensive assessment of maternal morbidities associated with OVD and episiotomy use from the third trimester of pregnancy to one year postpartum.

A strength of this follow up study is the longitudinal methodology used with data collected prospectively from the third trimester up to one year postpartum. This has rarely been done in RCTs or observational studies of OVD. Having baseline data available for comparison with postpartum data has revealed that although the morbidities studied are associated with OVD they are in fact in many cases as prevalent and in some cases more prevalent in the third trimester of pregnancy. It may be that morbidities previously attributed to OVD have in fact been present antenatally to greater or equal degrees.

Validated assessment tools were used to gain an in depth understanding of maternal morbidities and how they impact on the lives of women in the postpartum period. The questionnaires developed appeared to be easy to complete and the percentage of missing data was small (<5%), despite the respondent being instructed to miss out any question they did not feel comfortable completing.

Participating numbers were high in the antenatal, immediate postpartum period and at six weeks postpartum (99%, 92% and 83% respectively) but were less at one year postpartum (54%). The data from the descriptive analysis reassured us that although the response rate, especially at one year postpartum was less than at the earlier time points, there was no specific population from whom data were missing.

6.4.3 Comparison with existing literature

One longitudinal study on the prevalence of maternal morbidities at OVD with data collected in the antenatal period was identified in the literature (Wesnes et al. 2009). The study supports the findings of Wesnes et al. (2009) with regard to the antenatal prevalence of urinary and anal incontinence. They reported postpartum UI to be more likely if UI was present during pregnancy which the study supports. Reported rates of urinary morbidity in the study were in line with previously published studies (Sleep and Grant 1987; Glazener et al. 2006) but higher than those reported in Chaliha et al. (1999).

From studies of episiotomy use at SVD, (Sleep et al. 1984, Sleep and Grant 1987 and Klein et al. 1992) no differences in incidence of UI were found between the two approaches to episiotomy use. In contrast to this, findings suggest that a routine use of episiotomy at OVD may in fact offer some protection against urinary morbidities at six weeks postpartum, especially stress urinary incontinence.

No evidence is available from RCTs on the relationship between episiotomy use at OVD and AI however Fritel et al. (2008) in their quasi randomised trial reported that a policy of routine episiotomy was associated with a greater risk of AI compared to a restrictive policy four years after first delivery if flatal incontinence was included (16% vs 11%, p=0.04). This significant difference persisted for flatal incontinence alone (13% vs 8%, p=0.02) but

not for anal incontinence of solids (3% for both groups, p=0.94). Results do not support this finding as no differences were identified between approaches to episiotomy use with regard to anal incontinence of flatus, liquids or solids.

Similarly studies of episiotomy use at spontaneous delivery, most (Harrison et al. 1984, Sleep et al. 1984 and Klein et al. 1992) found there to be no differences in perineal pain or healing complications between a routine and a restrictive approach to episiotomy use while the Argentine Episiotomy Trial Collaborative Group (1993) reported that a selective approach to episiotomy use at vaginal delivery was associated with less perineal pain at hospital discharge than a routine approach, [RR 0.72(95%CI 0.65 – 0.81)]. Findings from this study contradict that evidence with a routine use of episiotomy being found to offer some protection against perineal pain in the immediate postpartum period. These differences in prevalence however had disappeared by six weeks postpartum. Perineal pain reported by completion of the McGill pain questionnaire identified that a routine use of episiotomy was associated with a significantly lower intensity of pain at six weeks postpartum compared to a restrictive approach to episiotomy. Healing complications were found to be equally likely with either approach to episiotomy use at OVD.

6.4.4 Implications for practice and future research

The novel longitudinal approach to data collection in this cohort study commencing in the antenatal period has revealed significant levels of morbidities which have historically been ascribed to operative delivery. This approach should be adopted in future research to better understand the role of episiotomy in the light of the prevalence of pre-existing morbidities.

The findings of the RCT analysis of maternal morbidities should be interpreted with care as this was a large pilot study primarily aimed at assessing the improved study design

informed by findings from the feasibility study and the possibility of conducting a multicentre study. A definitive study would require to recruit some 12000 women in the antenatal period which would result in 1600 women randomised to each arm. A sufficiently powered sub group analysis by instrument used, to assure results equally applicable to both vacuum and forceps delivery would require an even bigger study population.

Further work is required to provide women and their carers with high quality information regarding episiotomy use at OVD in terms of pelvic floor morbidity but meantime the study would support present practice.

Chapter 7 - Final summary and conclusion

It can not be assumed that the body of evidence collated in order to answer the question of the optimal approach to episiotomy use at SVD can be applied to OVD without a robust evaluation of the outcome measures of interest.

The aims of this series of studies were to:

1. Look at current practice of obstetricians in the UK and Ireland with regard to their approach to episiotomy use at OVD
2. To assess the feasibility of conducting an RCT of routine versus restrictive use of episiotomy at OVD
3. To gather data prospectively on the entire cohort of women delivering by OVD in the two study centres over the study period of the pilot RCT
4. To conduct a pilot RCT of routine versus restrictive use of episiotomy at OVD with follow up of maternal and infant morbidities to one year postpartum

This chapter summarises the findings of the four studies comprising the research project designed to address these aims and highlights the clinical and research implications of the thesis as a whole.

7.1 Summary of Findings

The national survey established that the majority of clinicians, irrespective of level of experience, would support the historical perspective that episiotomy is protective of anal sphincter trauma at forceps delivery. This relationship was however found to more in equipoise at vacuum extraction. Men were found to be more likely to believe that episiotomy use increases the risk of anal sphincter tearing at forceps delivery but decreases the risk at vacuum delivery.

Instrument preference was found to vary both with the station and position of the fetal head and with the level of experience and gender of the operator. Vacuum extraction was found to be the preferred instrument in both low and mid cavity non rotational delivery. No clear preference for instrument use was identified at rotational mid cavity delivery. Registrars were found to be significantly more likely to use vacuum than consultants at all stations and positions of the fetal head. Preference for vacuum was also noted among women respondents.

A restrictive use of episiotomy was found to be the respondents preferred approach at vacuum delivery and a routine use at forceps delivery. Data also suggest that the more experienced the operator the more likely they are to adopt a restrictive approach to the use of episiotomy in rotational vacuum and all types of forceps delivery whilst the approach in non rotational vacuum was similar across the experience spectrum. The respondents to this survey expressed a lot of interest in a potential RCT although some respondents felt that this was an issue for clinical judgement and could not be tested in a trial setting.

The feasibility study of an RCT of routine versus restrictive approach to episiotomy use at OVD has established the possibility of conducting research in this difficult environment, while identifying problems with the study design which would require to be addressed prior to the conduct of a definitive study. The study was found to be of interest to women with a high rate of participation among those approached. Assessment tools and measures were developed and were found to be easy to complete and acceptable to women. Some problems were encountered with targeting of recruitment to high risk groups and by reliance on staff out with the study team to undertake recruitment. A major limitation of the study was the high level of women recruited but not randomised when delivered by

OVD. Strategies were developed to attempt to mitigate for these shortcomings in a future trial.

The prospective cohort study of maternal and neonatal morbidity in relation to use of episiotomy at OVD found that the use of episiotomy at OVD was not associated with any reduction in the risk of anal sphincter tearing, shoulder dystocia or neonatal trauma as traditionally ascribed to it, however, it was associated with an increased risk of PPH, perineal infection and a greater use of moderate or strong analgesia up to the tenth postnatal day. Rates of adverse urinary and bowel symptoms were similar with or without use of episiotomy although longer term follow-up is required. Due to the shortcomings of this methodology it is possible that there are factors confounding the identified associations between episiotomy use at OVD and the maternal morbidities described. To address this issue would require the conduct of an RCT of episiotomy use at OVD which it was known would present challenges.

The two centred pilot RCT of routine versus restrictive approach to episiotomy use at OVD was not powered to detect significant differences in outcome measures however results suggested that a restrictive approach to use of episiotomy at OVD would not reduce or greatly increase anal sphincter tears compared to routine use. Routine use of episiotomy was however found to be associated with an increased incidence of PPH. Obstetricians are more liberal in their use of episiotomy at forceps than vacuum delivery and this did not appear to have any adverse consequences in terms of anal sphincter damage, perineal morbidity or neonatal complications.

Follow up analyses of the RCT reported de novo urinary incontinence to be significantly less associated with a routine approach than a restrictive approach to episiotomy use at OVD. A routine approach to use of episiotomy at OVD does not appear to increase and

may even decrease rates of urinary morbidity, in particular stress incontinence; dyspareunia; and perineal pain compared to a restrictive use.

7.2 Clinical Implications

As the decision whether or not to cut an episiotomy may have a profound impact on women's recovery, long-term health and psychological wellbeing following OVD it is important that pregnant women and obstetricians can base their decision making on robust evidence informing them of the likely impact of their actions. It has been established that the obstetrician's perception of the relationship between episiotomy use and anal sphincter tears influences his/her use of episiotomy. It is therefore vital that he/she is well informed regarding the possible sequelae of a routine or restrictive approach to episiotomy use.

A routine approach to episiotomy use has historically been the preferred approach with the aim of avoiding anal sphincter tears and associated maternal morbidities of pain, haemorrhage, healing difficulties, urinary and anal incontinence and dyspareunia.

The findings of this pilot RCT would support the continued use of a routine approach to episiotomy use at forceps delivery meantime, pending the results of a definitive study, as there would appear to be no significant increase in the incidence of anal sphincter tears with this approach to episiotomy use at OVD. There would appear to be no detrimental effect on associated perineal morbidities or neonatal complications, indeed some protection may be afforded certain longer term morbidities such as de novo urinary incontinence postpartum, urinary stress incontinence and perineal pain. Primary postpartum haemorrhage however was identified as being possibly more likely with a routine approach to episiotomy at OVD. This data should forearm operators allowing measures to be taken to minimise bleeding e.g. cutting the episiotomy as late as possible

in the delivery to allow maximum stretching of the perineum and timely suturing of the episiotomy.

7.3 Research Implications

The conduct of this pilot RCT has demonstrated the possibility of conducting such a study. This pilot RCT was not however powered to provide definitive information on its primary and secondary outcome measures. A definitive study is required to provide robust evidence on which operators can base their practice regarding episiotomy use at OVD. If results of a definitive RCT found a restrictive use of episiotomy at OVD to be favourable then it may be that this trial would be an interim step to a comparison of a restrictive use versus no episiotomy at OVD. There is currently no evidence on which to base identification of circumstances in which it is essential to use episiotomy and there have been no conclusions drawn from the literature on what the optimal episiotomy rate should be. For clinical practice in the future it would be useful to have established sufficient evidence to inform guidelines for obstetricians indicating circumstances in which the use of episiotomy could be recommended.

A definitive trial to address the primary outcome measure of anal sphincter tears would need to adopt a multi centred approach as it would have to recruit some 12000 women in the antenatal period, which would result in 1600 randomised women in each arm. This calculation is based on the absolute difference of 2.8% that was found between groups in the pilot RCT with regard to anal sphincter tearing (8.1% routine vs 10.9% restrictive groups respectively) and the ratio of women recruited to those on whom a decision was made to deliver by OVD.

A sufficiently powered sub group analysis by instrument used to assure results equally applicable to both vacuum and forceps delivery would require an even bigger study

population. Due to the apparent difference in effect size and direction between the study arms with regard to anal sphincter tearing, our primary outcome measure, observed in the pilot RCT (8.3% routine vs 0% restrictive at vacuum delivery; 9.8% routine vs 16.4% restrictive at forceps delivery) it might be prudent in a definitive study to establish the required sample size for each instrument independently. It would be unethical to recruit more women than were necessary to establish definitive data. Based on the data observed in the pilot RCT a definitive multi centred trial would require to randomise in the order of 900 women undergoing forceps delivery. Likewise such a trial would require to randomise 226 women undergoing vacuum delivery. These numbers could be recruited in two separate trials or in one trial as long as the randomisation program was stratified by instrument to ensure equal allocation to each study arm.

With the sea change in approach to episiotomy use at SVD that has taken place in recent years and some evidence of this influencing the approach to episiotomy at OVD despite the paucity of any rigorous examination of the implications for women and their infants it is therefore timely that such a study be conducted to ensure women and their accoucheur are able to make an informed decision regarding the optimal use of episiotomy at OVD.

7.4 Conclusion

This thesis reports on a body of research that examined two approaches to the use of episiotomy currently within practice in the UK, routine use which has historically been the approach of choice at OVD and restrictive use which is recommended at SVD but which has not been robustly evaluated at OVD. The findings of the research as a whole reveal both advantages and disadvantages with a routine approach to episiotomy use at OVD. The data is leaning towards a routine approach for forceps and as such would support

current practice with regard to approach to episiotomy use at OVD meantime. Until definitive evidence is available clinicians should use clinical judgement on whether or not to use episiotomy. Recommendations for clinical practice and future research from this research have been highlighted. Implementation of these recommendations would facilitate optimal use of episiotomy at OVD and help improve outcomes for postpartum women and their infants.

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Appendices

Appendix 1 Timeline of key events

Year	Month	Study	Task
2003	Jan	Feasibility study	Protocol development
2003	June	Feasibility study	Application for funding
2003	August	Feasibility study	Submission for ethical and management approval
2003	November	Feasibility study	Approvals granted. Recruitment commences
2003	November	questionnaire	Application for funding
2003	December	Feasibility study	Randomisation commences
2004	Jan	questionnaire	Development of questionnaire
2004	March	Pilot RCT	Application for funding
2004	April	Feasibility study	Randomisation ends, data entry and analysis
2004	April	Pilot RCT	Protocol development
2004	June	Pilot RCT	Finalising study documents, submission for ethical approval, sponsor status and management approval
2004	August	Pilot RCT	Ethical and management approval granted
2004	August	questionnaire	Survey 1st round
2004	September	Pilot RCT	Recruitment commences - Dundee
2004	September	cohort	cohort study commences
2004	October	Pilot RCT	Randomisation commences - Dundee
2004	November	questionnaire	Survey final round
2005	June	Pilot RCT	Recruitment commences - Bristol
2005	July	Pilot RCT	Randomisation commences - Bristol
2005	October	1 year folow up	1 year follow up starts
2006	June	Pilot RCT	No cost extension approved
2006	September	Pilot RCT	Randomisation ends - Dundee
2006	September	Pilot RCT	Randomisation ends – Bristol, data entry and analysis
2006	September	cohort	Cohort study ends, data entry and analysis
2006	November	1 year follow up	Application for further funding
2007	September	1 year follow up	1 year follow up ends, data entry and analysis

Appendix 2 Members of the study team

Name	Initials	Job Title	Location during study period
Rachna Bahl	RB	Specialist Registrar	St. Michael's Hospital, Bristol
Karen Goyder	KG	Research Midwife	St. Michael's Hospital
Louise Howarth	LH	Research Midwife	St. Michael's Hospital
Katie Macleod	KM	Data entry	University of Dundee
Maureen Macleod	MM	Research Midwife	University of Dundee
Deirdre Murphy	DM	Professor of Obstetrics	University of Dundee
Simon Ogston	SO	Statistician	University of Dundee
Bryony Strachan	BS	Consultant Obstetrician	St. Michael's Hospital
Maud Van de Venne	MV	Specialist Registrar	St. Michael's Hospital

Appendix 3 Contributions of study team members

Task	Major Contribution
Original concept	DM
Development of protocol	DM, MM
Gaining funding	DM, MM, BS
Obtaining ethical and management approvals	DM, MM, RB, BS
Conduct of national questionnaire survey	DM, MM
Development of baseline and follow up questionnaires	DM, MM
Development of Randomisation program	SO
Recruitment to feasibility study	MM
Data collection and entry– feasibility study	MM
Feasibility study data analysis	DM, MM
Recruitment to pilot RCT	MM, KG, LH
Data Collection – cohort study, pilot RCT datasheets, followup questionnaires	MM, KG, LH, RB, MV
Data entry and data cleaning cohort study and pilot RCT	KM, MM
Pilot RCT data analysis	DM, MM
Reporting of SAE	MM, LH
Writing of publications, Reports to ethics committee and funder	DM, MM, BS

Appendix 4 Postal Questionnaire - A National Survey Of Clinical Practice

USE of EPISIOTOMY in INSTRUMENTAL DELIVERY- OBSTETRICIAN'S QUESTIONNAIRE

Study Number ☐

Please provide a response to EACH of the following statements unless you feel this questionnaire is not applicable to you. If so, please tick the box below and indicate why.

Not Applicable ☐ Why? .....

.....

We plan to develop a Randomised Controlled Trial comparing Restrictive(when tearing becomes apparent) versus Routine(in all cases) Use of Episiotomy in Instrumental Delivery and would welcome your views:

What do you perceive as the relationship between the use of Episiotomy and the risk of 3°/4° tear in Forceps delivery?

Increases risk ☐ Decreases risk ☐ No Difference ☐ Don't know ☐

What do you perceive as the relationship between the use of Episiotomy and the risk of 3°/4° tear in Ventouse Delivery?

Increases risk ☐ Decreases risk ☐ No Difference ☐ Don't know ☐

Can you suggest any elements of practice you would like to see evaluated in such a trial?

.....

.....

.....

.....

PART ONE

How would you manage a labour with **low cavity arrest**, a fetal **OA** position and no signs of cephalopelvic disproportion or fetal distress?

	Always	Frequently	Rarely	Never
I would use the Ventouse	☐	☐	☐	☐
I would use Forceps	☐	☐	☐	☐

Please add any comments you may have regarding your response to this question.

……

……

……

How would you manage a labour with **mid cavity arrest**, a fetal **OA** position and no signs of cephalopelvic disproportion or fetal distress?

I would use the Ventouse	☐	☐	☐	☐
I would use Forceps	☐	☐	☐	☐

Please add any comments you may have regarding your response to this question.

……

……

……

How would you manage a labour with **mid cavity arrest**, a fetal **OT or OP** position and no signs of cephalopelvic disproportion or fetal distress?

I would use rotational Ventouse	☐	☐	☐	☐
I would perform manual rotation + forceps	☐	☐	☐	☐
I would use rotational Forceps	☐	☐	☐	☐
I would perform a Caesarean Section	☐	☐	☐	☐

Please add any comments you may have regarding your response to this question.

……

……

PART TWO

We are interested in your current practice with regard to your use of episiotomy at instrumental delivery. The three options are **- restrictive use** (only if tearing becomes apparent), **routine use** (in all cases) or never use episiotomy.

	Routine	Restrictive	Never	Not applicable
What is your current practice regarding episiotomy and non rotational Ventouse delivery?	☐	☐	☐	☐
What is your current practice regarding episiotomy and rotational Ventouse delivery?	☐	☐	☐	☐
What is your current practice regarding episiotomy and Low cavity forceps delivery?	☐	☐	☐	☐
What is your current practice regarding episiotomy and non rotational midcavity forceps delivery?	☐	☐	☐	☐
What is your current practice regarding episiotomy and Rotational forceps delivery?	☐	☐	☐	☐

Please add any comments you may have regarding your response to this question.

……..

……..

……..

PART THREE

Would you be willing to take part in a trial of Restrictive vs Routine use of episiotomy Yes ☐ No ☐ Not Applicable ☐

If your response is NO please indicate why……

……

……

……

……

PTO

Please provide the following information about yourself:

Age: <30 ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ ≥60 ☐

Male ☐ Female ☐

Grade: Consultant ☐ SpR4-5+ ☐ SpR1-3 ☐ SSHO ☐
Associate Specialist ☐ Staff Grade ☐

MRCOG: Yes ☐ **No** ☐ **FRCOG: Yes** ☐ **No** ☐

Thank you for your time and co-operation.

Appendix 5 Letter To RCOG Requesting Purchase Of The Database Of Obstetricians Practicing In UK And Ireland

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY.

Dear Andrea,

Following our correspondence at the end of last year, we have now secured charity funding (Anonymous Trust Grant) for our postal questionnaire and so are in a position to proceed with requesting a copy of your database of all Obstetric consultants, SpR's and trainees currently practicing within the UK. You previously indicated this would hopefully be charged at the "Charitable Status" rate of £329.35 dependant on the decision made by your Honorary Secretary.

I have enclosed a sample of our questionnaire and covering letter for your approval.

Should you require any further assistance in proceeding with this request please do not hesitate to contact me.

Yours sincerely,

Maureen Macleod
Research Midwife

Appendix 6 Cover Letter - A National Survey Of Clinical Practice

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY.

Dear Colleague,

The instrumental vaginal delivery rate in the United Kingdom is currently between 12 and 15% but limited research has been carried out addressing the optimal conduct of such deliveries.

In particular, we are interested in the use of episiotomy in instrumental delivery, which is associated with individual variation from practitioner to practitioner.

To enable us to achieve an overview of current practice within the United Kingdom, we would request your assistance in completing the enclosed questionnaire. This should only take a few minutes of your time, which we appreciate is at a premium. Once completed, please return in the stamped addressed envelope provided. If the questionnaire is not relevant to your clinical practice, please return it uncompleted to prevent further attempts being made to retrieve the information.

Your responses are vital to the validity of the survey conclusions as a high response rate is the only way of achieving statistically sound results.

Thank you for your help.

Yours sincerely,

Deirdre Murphy
Professor of Obstetrics and Gynaecology

Maureen Macleod
Research Midwife

Appendix 7 Reminder Letter For Non Reponders - A National Survey Of Clinical Practice

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY.

Dear Colleague,

Please find enclosed a questionnaire, which we previously sent you, but have not as yet received completed. We are aware your time is very limited but if you could spare just a few minutes to complete the questionnaire and return it in the prepaid envelope provided we would be very grateful.

If you are opening this letter on behalf of an addressee who has moved away, would you be so kind as to tick the *Not Applicable* box at the head of the questionnaire and return it to us in the prepaid envelope.

A great many clinicians have already responded but to maximise the validity of the survey conclusions we would urge you to return the questionnaire.

Thank you for your time.

Yours sincerely,

Deirdre Murphy
Professor of Obstetrics & Gynaecology

Maureen Macleod
Research Midwife

Appendix 8 Patient Information Sheet – Feasibility Study

Restrictive vs Routine Use of Episiotomy in Instrumental Delivery

Patient Information Sheet

You are being invited to take part in a research study. Before you decide to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others. Please ask us if there is anything that is not clear or about which you would like more information.

Who is organising and funding the research?

The study is being organised jointly by the University of Dundee and Ninewells Hospital. The Tayside University Hospitals Grant Scheme funds it.

What is the purpose of the study?

The purpose of the study is to look at two different approaches to the use of episiotomy- a cut to widen the vaginal opening- when women need a forceps or vacuum delivery. There are some risks and benefits for both mother and baby associated with each approach and we are trying to find out which is the best option to use when doing a forceps/vacuum delivery. We want to find out the best way to use episiotomy giving women and doctors/midwives information about the various risks and benefits in order to help them decide what to do in this circumstance. The two options that are being compared are **- restrictive use** (only if tearing becomes apparent) and **routine use** (in all cases). Both methods are in normal obstetric practise but vary from doctor to doctor. Women are becoming more and more involved in their own health care and it is important that decisions can be based on sound evidence. The purpose of this study is to help us understand what is the best use of episiotomy when performing an instrumental delivery.

Why have I been chosen?

We are carrying out the initial part of this study in the maternity unit in Dundee. We are trying to contact every woman who is booked to deliver in this hospital by a normal vaginal delivery. 1 in 8 women who plan to deliver normally however need a forceps or vacuum delivery and if this decision is made with you, it is at that point you would be allocated to a specific type of episiotomy use. Over the next 4 months we hope to have around 50 women like you taking part in the study.

Do I have to take part?

It is entirely your choice whether you take part or not. If you do decide to take part you will be given this information sheet to take home and will be asked to sign a consent form. You will of course be free to change your mind at any time and this will not affect the way we look after you. If you decide not to take part, your delivery will be managed in the usual way through discussion with your obstetrician and midwife.

The Tayside Committee on Medical Research Ethics, which has a responsibility for looking at all proposed research studies on humans in Tayside has examined this study and raised no objections to it. It is a requirement that your records in this research and any relevant medical

records be made available for scrutiny by monitors from the TUHT scheme, NHS Tayside and the regulatory authorities.

What will happen during the study?

Everyone that agrees to take part in the study will, if a decision is made to deliver them by forceps/vacuum, be allocated by chance to one of two ways of using episiotomy as part of their delivery. Then the two groups will be compared at the end of the study to find out which one, if any, best helps women and babies to make an uncomplicated recovery following delivery. Depending on which group you are in you will be managed with:
1.A **Restrictive** approach when episiotomy is only used if tearing of the birth canal appears to be happening.
2. a **Routine** approach when episiotomy will be performed in all cases to avoid tearing.

In both groups you will be asked to complete a questionnaire before your baby is born, the day or two after birth and six weeks after birth to let us know about your recovery and your baby's progress. You will also be invited back to Ninewells for a postnatal appointment 6 weeks after your baby is born to discuss your recovery from delivery.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. A researcher on the study will need to look at your hospital records for information about your method of delivery. All information about you that leaves the hospital will have your name removed so that you cannot be recognised by it. We will ask for your consent to inform your GP that you are taking part in the study.

What will happen to the results of the study?

The study will last for 6 months in the first instance. If it is successful we hope to extend it to other hospitals in order to test this research question in the greatest number of cases possible. We hope the results will provide clear information for women and their obstetricians about their options at the time of instrumental delivery. A report will be produced at the end of the study and the main results will be published in medical journals. This can take up to a year after the end of the study but if you would like a copy of the results please let us know.

Contact for further information:

Maureen Macleod,
Research Midwife,
Ninewells Hospital.
01382 660111 (Bleep 4811)
e mail: m.macleod@dundee.ac.uk

Thank you for your consideration of this study as without you it would not be possible.

Appendix 9 Consent Form – Feasibility Study

Restrictive vs Routine Use of Episiotomy in Instrumental Delivery

Consent Form

1. I have read the information sheet for the above study and have had an opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving a reason, without my medical care or legal rights being affected. ☐
3. I give permission for sections of my medical notes to be looked at by a researcher to obtain information relevant to the study. I understand that all information will remain strictly confidential. ☐
4. I agree that all information collected about me as part of the study can be stored and analysed by the research team at the University of Dundee ☐
5. I give permission for my GP to be informed about my participation in this study. ☐
6. I agree to take part in the above study. ☐

_____	_____	_____
Name of participant	Signature	Date of signing

_____	_____	_____
Name of researcher	Signature	Date of signing

Appendix 10 Baseline Questionnaire – Feasibility/Pilot Study

RESTRICTIVE vs ROUTINE USE of EPISIOTOMY in INSTRUMENTAL DELIVERY

VOLUNTEER QUESTIONNAIRE – ANTENATAL

STUDY No. ☐

Thank you very much for taking the time to complete this questionnaire. We hope it won't be too difficult to fill out but if you have any comments regarding the questionnaire please add them below. Please feel free to leave out any question you do not feel comfortable answering. Your help is very much appreciated.

.....
.....
.....

Urinary Symptoms

Do you ever have a problem with urine leaking? Yes ☐ No ☐

If you have urine leakage, how long ago did it begin? Months ☐ Years ☐ (Please insert a number)

Do you regularly perform pelvic floor exercises? Yes ☐ No ☐

Now think about the last week.....

During the day, how many times do you pass urine on average?	1-6 times ☐ 7-8 times ☐ 9-10 times ☐ 11-12 times ☐ 13+ times ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you have to rush to the toilet to pass urine?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Does urine leak before you can get to the toilet?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
How often do you leak urine?	Never ☐ Once or less per week ☐ 2-3 times per week ☐ Once a day ☐ Several times a day ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

Does urine leak when you are physically active, exert yourself, cough or sneeze?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

Do you leak urine for no obvious reason and without feeling that you want to go?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

If you do change, what do you usually need to change?	Underclothes ☐ Panty liners/minipads ☐ Maxi/Super pads ☐ Nappies/Incontinence products ☐ Other-please specify ☐	How many times a day do you change the ticked items because of leakage?	No change ☐ Once ☐ 2-3 times ☐ 4-5 times ☐ More than 5 times ☐

Please describe any other urinary changes you have noticed……

……

……

Problems with Intercourse

Do you ever experience pain on intercourse? **Yes** ☐ **No** ☐

Did you experience any pain the last time you had intercourse? **No** ☐ **Mild** ☐ **Moderate** ☐ **Severe** ☐

Has the pain prevented you from having intercourse? **Yes** ☐ **No** ☐

Bowel Problems

Please think about how you have been in the last week:

Do you ever leak wind from your bowels without control?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you ever leak liquid from your bowels without control?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you ever leak solid from your bowels without control?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you ever wear pads because of leakage from your bowels?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Have bowel problems altered your lifestyle?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

Do you have to rush to the toilet to move your bowels? **Yes** ☐ **No** ☐

Can you wait at least 5 minutes? **Yes** ☐ **No** ☐

How Do You Feel?

Please underline the answer that comes closest to how you have felt in the last week.

I have been able to laugh and see the funny side of things:
- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

I have looked forward with enjoyment to things:
- As much as I ever did
- Rather less than I used to
- Definitely less than I used to
- Hardly at all

I have blamed myself unnecessarily when things went wrong:
- Yes, most of the time
- Yes, some of the time
- Not very often
- No, never

I have been worried or anxious for no good reason:
- No, not at all
- Hardly ever
- Yes, sometimes
- Yes, very often

I have felt scared or panicky for no good reason:
- Yes, quite a lot
- Yes, sometimes
- No, not much
- No, not at all

Things have been getting on top of me:
- Yes, most of the time I haven't been able to cope at all
- Yes, sometimes I haven't been able to cope as well as usual
- No, most of the time I have coped quite well
- No, I have been coping as well as ever

I have been so unhappy that I have had difficulty sleeping:
- Yes, most of the time
- Yes, sometimes
- Not very often
- No, not at all

I have felt sad or miserable:
- Yes, most of the time
- Yes, quite often
- Not very often
- No, never

I have been so unhappy I have been crying:
- Yes, most of the time
- Yes, quite often
- Only occasionally
- No, never

The thought of harming myself has occurred to me:
- Yes, quite often
- Sometimes
- Hardly ever
- Never

Thank you!

Appendix 11 GP Notification Letter – Feasibility/Pilot Study

Dept. of Maternal & Child Health Sciences 2,
Ninewells Hospital & Medical School,
Dundee DD1 9SY
Tel: 01382 632979
E mail: m.macleod@dundee.ac.uk

Dear Dr ……,

Randomised controlled trial of restrictive versus routine use of episiotomy for instrumental vaginal delivery – a two-centre pilot study

I am writing to inform you that your patient, ……., has agreed to take part in a research study being conducted jointly by the University of Dundee, Ninewells Hospital, Dundee and St. Michael's Hospital, Bristol. Funding is by Tenovus Scotland.

The objective of the study is to evaluate two different approaches to the use of episiotomy when women require an instrumental vaginal delivery – either forceps or ventouse. Two interventions are being compared; restrictive use of episiotomy (only used if tearing becomes apparent) or routine use (in all cases). These two approaches have had no formal evaluation to date, however, both are part of standard obstetric practice with variation in preference by individual clinicians. The experience of obstetricians participating in the study will reflect the normal mix on a labour ward at any time but at all times inexperienced operators will be supervised by their more experienced colleagues. Eligible women are recruited in the third trimester of pregnancy and their consent to participate will again be confirmed on admission to the labour ward. Should instrumental delivery be required, they will be randomised at that point to one of the two possible interventions.

Women will be asked to complete questionnaires (4 in total) - antenatally, one/two days postnatal, 6 weeks postnatal and one year postnatal. From these we will evaluate the outcome for the mother and baby. Postnatal review will otherwise be as usually indicated.

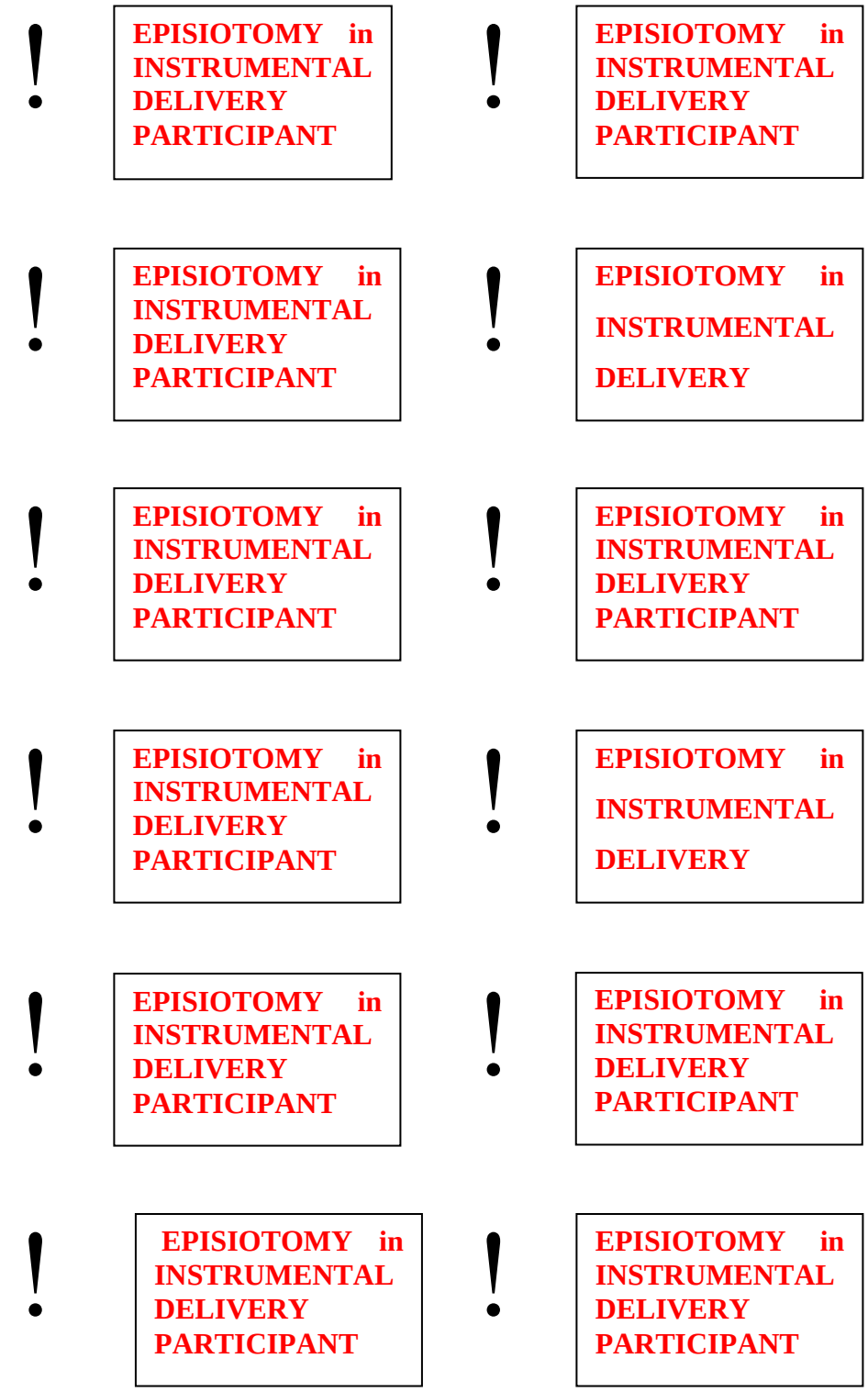
We anticipate that any requests by women for additional appointments to discuss mode of delivery will mostly be with the obstetric team in hospital, however, it is possible that this patient may seek an appointment with either you or the community midwife to further discuss the risks and benefits of instrumental delivery and episiotomy.

If you have anything that you would like to discuss, either about the study in general, or this patient in particular, please do not hesitate to contact me.

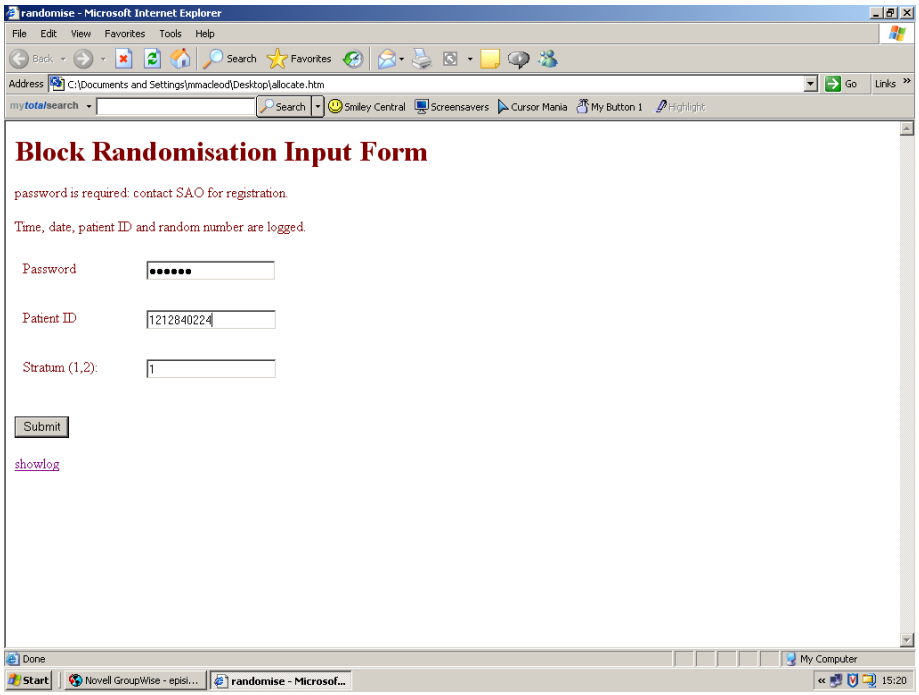
Yours sincerely,

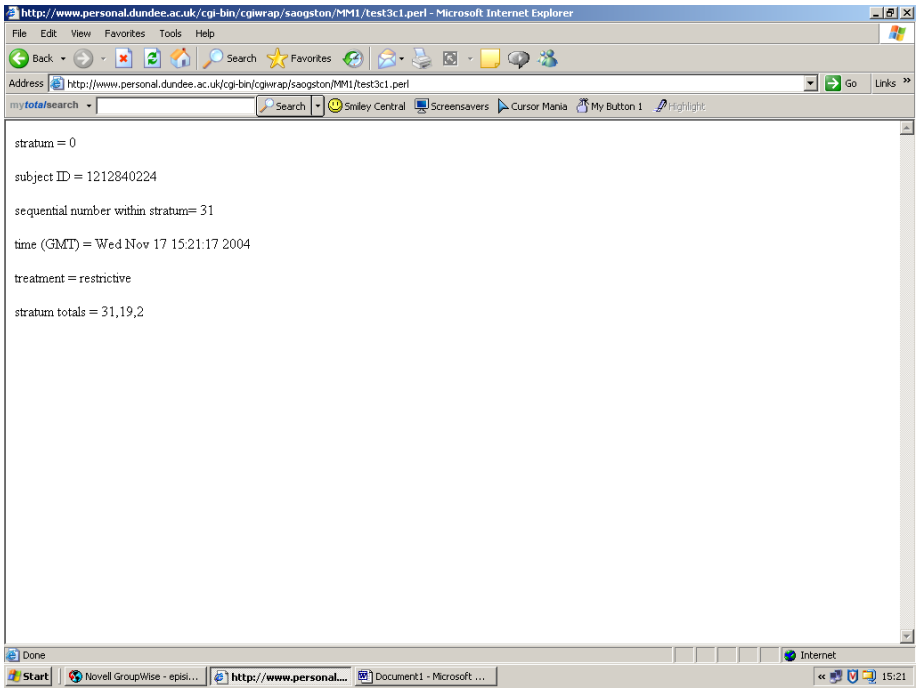
Maureen Macleod
Research Midwife and Study Co-ordinator

Appendix 12 Case Note Sticker – Feasibilty Study



Appendix 13 Screen Prints Of Randomisation Program – Feasibility/Pilot Study





Appendix 14 Randomisation Instruction Poster – Feasibility Study

EPISIOTOMY TRIAL

This woman has consented to participate in the above trial.

If she is to be delivered instrumentally RANDOMISE

Double click on Episallocate icon on computer at LS desk

Insert password – maureenm

Enter woman's CHI number

Leave Stratum as 1

Press submit

Allocation will be to:

Routine Episiotomy-
in all cases

or

Restrictive Episiotomy-
only if tearing imminent or clinically indicated

Appendix 15 Data Extraction Proforma – Feasibilty/Pilot Study

RCT Data Sheet

Restrictive VS Routine Use of Episiotomy in Attempted Instrumental Delivery

Study No. ☐ **Group** ☐ **Site** ☐ **Patient Initials** ☐

MPI ☐ **Parity** ☐ + ☐ **Age** ☐

EDD ☐ **Postcode** ☐

Booking Weight (kg) ☐ **Height (cm)** ☐ **BMI** ☐

Medical Conditions

Smoking: No ☐ 1-10 ☐ 11-20 ☐ >20 ☐

Alcohol: Units per week: Pre pregnancy ☐ During Pregnancy ☐

Drug Abuse: None ☐ NonIVDU ☐ IVDU ☐

Complications of Current Pregnancy (please circle) None

PET	Polyhydramnios	Fetal Abnormality
IUGR	Oligohydramnios	Placenta Praevia
APH	Infection	Urinary incontinence y /n /dk

Other……

Labour: Spontaneous onset ☐ Induced ☐ Type of IOL ☐ Augmented ☐

Confirmed Gestation: ☐☐ + ☐

Pyrexia in labour(>38°): Yes ☐ No ☐

Liquor: Clear ☐ Meconium ☐ Purulent ☐ Malodourous ☐

Intrapartum Haemorrhage: No ☐ Yes ☐ <5ooml ☐ >500ml ☐ Abruption ☐ Placenta Praevia ☐

Intrapartum analgesia: Tens ☐ Inhalation ☐ Parenteral ☐ Epidural ☐

Oral ☐ Specify …….. Pudendal block ☐ Spinal ☐ GA ☐

CTG Abnormalities: (As defined by NICE guidelines)

	1st Stage	2nd Stage
Bradycardia	☐	☐
Tachycardia	☐	☐
Decelerations- Variable	☐	☐
Decelerations- Late	☐	☐
Reduced Variability	☐	☐

Length of: 1st Stage (hours) ☐ 2ndStage (mins) ☐ Active pushing (mins) ☐

Mode of Delivery:

Attempt	1	2	3
Ventouse (NR)	☐	☐	☐
Ventouse (R)	☐	☐	☐
Low Cavity Forceps	☐	☐	☐
Mid cavity (NR)	☐	☐	☐
Rotational Forceps	☐	☐	☐
Caesarean Section	☐	☐	☐
Instrument Used	☐	☐	☐
Manual Rotation	☐	☐	☐

Indication for OVD: List in order of priority

1. Delay ☐ 2. Fetal Distress ☐ 3.Malposition ☐ 4.Other……

Decision to delivery time (mins): ☐

Grade of Operator 1: SHO ☐ SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐

Grade of Supervisor: SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐ None ☐

Grade of Operator 2: SHO ☐ SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐

Grade of Supervisor: SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐ None ☐

Grade of Operator 3: SHO ☐ SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐

Grade of Supervisor: SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐ None ☐

Sutured by: SHO ☐ SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐

Position diagnosed at Outset: OA ☐ OT ☐ OP ☐

Position at Delivery: OA ☐ OT ☐ OP ☐

Station: 0 ☐ +1 ☐ +2 ☐ +3 ☐

Moulding: None ☐ Mild/Mod (+1/+2) ☐ Severe (+3) ☐

Caput: None ☐ Mild/Mod ☐ Severe ☐

No. Pulls ☐ **No. Contractions** ☐

<u>Early Maternal Complications</u>

EBL ☐ 1° PPH ☐ 2° PPH ☐ Transfusion ☐ No units transfused ☐

Perineal Trauma: None ☐ Vag Wall laceration ☐ Cervical Laceration ☐

Labial laceration ☐ 1° Tear ☐ 2° Tear ☐

3°a Tear ☐ 3°b Tear ☐ 3°c Tear ☐ 3° unspecified ☐ 4° Tear ☐

Episiotomy ☐ Extended Episiotomy ☐

Until Hospital Discharge:
Perineal Infection ☐ Haematoma ☐ Resutured / Drained ☐

Antibiotics ☐ **Reason for antibiotics** ……..

Analgesia: Inpatient Strong ☐ Moderate ☐ Mild ☐

Outpatient Strong ☐ Moderate ☐ Mild ☐

Bladder
Blood Stained Urine ☐ Catheter>24hrs ☐ How long? (Days) ☐

Neuropathic/Retention ☐ UTI ☐ Incontinence ☐

Altered sensation ☐

Bowel

Neuropathic sphincter ☐ Incontinence of flatus ☐ Incontinence of faeces ☐

Postnatal inpatient days ☐

Maternal readmission Y/N Describe…….

Baby Details **Identification No.** ☐ **Time of Del** ☐

Birthweight ☐ **Calculated BW centile** ☐ **Head Circumference** ☐

Sex: Male ☐ Female ☐

Apgars: 1 min ☐ 5 min ☐ 10 min ☐

Cord Gases:

Arterial	pH				.		
	BE				.		
Venous	pH				.		
	BE				.		

Resuscitation:
Nil (incl suction+O2) ☐ IPPV<10mins ☐ IPPV>10mins ☐ Cardiac massage ☐

Time to 1st Spontaneous Breath: ☐

Trauma: - Bruising: No ☐ Mild ☐ Mod ☐ Severe ☐

Laceration: No ☐ Mild ☐ Mod ☐ Severe ☐

Encephalopathy: No ☐ Mild ☐ Mod ☐ Severe ☐

Cephalhaematoma: - Yes ☐ No ☐

Retinal Haemorrhage: - Yes ☐ No ☐

Brachial Plexus Injury: - Yes ☐ No ☐

Shoulder Dystocia: - Yes ☐ No ☐

Fracture: - Yes ☐ No ☐

Other……

Admission to NICU: Yes ☐ No ☐

Duration of Stay: Days ☐ Weeks ☐

Baby Follow Up Yes ☐ No ☐

Discharge Status: Normal ☐ Abnormal ☐ Suspect ☐ Neonatal Death ☐

Baby readmission Y/N Describe……

Any other relevant information ……

……

……

……

Appendix 16 1st / 2nd Day Questionnaire – Feasibility / Pilot Study

Randomised controlled trial of restrictive versus routine use of episiotomy for instrumental vaginal delivery – a two-centre pilot study

VOLUNTEER QUESTIONNAIRE – 1st DAY POSTNATAL

STUDY No. ☐

Thank you very much for taking the time to complete this questionnaire at such a busy time. We hope it won't be too difficult to fill out but if you have any comments regarding the questionnaire please add them below. Please feel free to leave out any question you do not feel comfortable answering. Your help is very much appreciated.

……
……
……

How Do You Feel?

Please underline the answer that comes closest to how you have felt since delivery.

I have been able to laugh and see the funny side of things:
As much as I always could
Not quite so much now
Definitely not so much now
Not at all

I have looked forward with enjoyment to things:
As much as I ever did
Rather less than I used to
Definitely less than I used to
Hardly at all

I have blamed myself unnecessarily when things went wrong:
Yes, most of the time
Yes, some of the time
Not very often
No, never

I have been worried or anxious for no good reason:
No, not at all
Hardly ever
Yes, sometimes
Yes, very often

I have felt scared or panicky for no good reason:
Yes, quite a lot

Yes, sometimes
No, not much
No, not at all

Things have been getting on top of me:
Yes, most of the time I haven't been able to cope at all
Yes, sometimes I haven't been able to cope as well as usual
No, most of the time I have coped quite well
No, I have been coping as well as ever

I have been so unhappy that I have had difficulty sleeping: Yes, most of the time
Yes, sometimes
Not very often
No, not at all

I have felt sad or miserable: Yes, most of the time
Yes, quite often
Not very often
No, never

I have been so unhappy I have been crying: Yes, most of the time
Yes, quite often
Only occasionally
No, never

The thought of harming myself has occurred to me: Yes, quite often
Sometimes
Hardly ever
Never

Pain Level

We would like you to indicate on the scale below how good or bad the pain from your perineum is today by drawing a cross at whichever point best indicates how you feel.

0 –I –I –I –I -10-I –I –I –I -20-I –I –I –I -30-I –I –I –I -40-I –I –I –I -50-I –I –I –I -60-I –I –I –I -70-I- I- I- I- 80-I- I- I- I- 90-I –I –I –I -100
least imaginable pain worst imaginable pain

What does your pain feel like?

Some of the words below describe your present pain. Circle ONLY those words that best describe it. Leave out any category that is not suitable. Use only a single word in each appropriate category- the one that best applies.

1	2	3	4
Flickering	Jumping	Pricking	Sharp
Quivering	Flashing	Boring	Cutting
Pulsing	Shooting	Drilling	Lacerating
Throbbing		Stabbing	
Beating		Lancinating	
Pounding			

5	6	7	8
Pinching	Tugging	Hot	Tingling
Pressing	Pulling	Burning	Itchy
Gnawing	Wrenching	Scalding	Smarting
Cramping		Searing	Stinging
Crushing			

9	10	11	12
Dull	Tender	Tiring	Sickening
Sore	Taut	Exhausting	Suffocating
Hurting	Rasping		
Aching	Splitting		

13	14	15	16
Fearful	Punishing	Wretched	Annoying
Frightful	Gruelling	Blinding	Troublesome
Terrifying	Cruel		Miserable
	Vicious		Intense
	Killing		Unbearable

17	18	19	20
Spreading	Tight	Cool	Nagging
Radiating	Numb	Cold	Nauseating
Penetrating	Drawing	Freezing	Agonising
Piercing	Squeezing		Dreadful
	Tearing		Torturing

How does your pain change with time?

Which word or words would you use to describe the pattern of your pain?

1	2	3
Continuous	Rhythmic	Brief
Steady	Periodic	Momentary
Constant	Intermittent	Transient

What kinds of things relieve your pain?

……

What kinds of things increase your pain?

……

How strong is your pain?

People agree that the following 5 words represent pain in increasing intensity. They are:

1	2	3	4	5
Mild	Discomforting	Distressing	Horrible	Excruciating

To answer each question below, write the number of the most appropriate word in the space beside the question.

Which word describes your pain right now? …….

Which word describes it at it's worst? …….

Which word describes it at it's least? …….

Which word describes the worst toothache you have ever had? …….

Which word describes the worst headache you have ever had? …….

Which word describes the worst stomach-ache you have ever had? …….

If given the choice would you take part in this study again? Yes ☐ No ☐ Don't know ☐

Thank you!

Appendix 17 6 Week Questionnaire – Feasibility/Pilot Study

Randomised controlled trial of restrictive versus routine use of episiotomy for instrumental vaginal delivery – a two-centre pilot study

VOLUNTEER QUESTIONNAIRE – 6 WEEKS POSTNATAL

STUDY No. ☐

Thank you very much for taking the time to complete this questionnaire at such a busy time. We hope it won't be too difficult to fill out but if you have any comments regarding the questionnaire please add them below. Please feel free to leave out any question you do not feel comfortable answering. Your help is very much appreciated.

.....
.....
.....

Your Baby's Health

Have you taken your baby to the Dr or back to hospital since he/she was born? Yes ☐ No ☐

If yes, why? .....

Was he/she admitted to hospital? Yes ☐ No ☐

Did he/she have any treatment there? Yes ☐ No ☐

What?.....

How are you feeding your baby? Breast ☐ Bottle ☐ Mixed ☐

Your Health

Have you gone to the Dr or returned to hospital since your baby was born for any delivery related complications? Yes ☐ No ☐

If yes,why?..... .....

Were you admitted to hospital? Yes ☐ No ☐ Why?.....

Did you have any treatment Yes ☐ No ☐ What?.....

Have you received any antibiotics for any delivery related infection? Yes ☐ No ☐

Why?.....

Urinary Symptoms

Do you ever have a problem with urine leaking? Yes ☐ No ☐

If you have urine leakage, how long ago did it begin? Months ☐ Years ☐
(Please insert a number)

Do you regularly perform pelvic floor exercises? Yes ☐ No ☐

Now think about the last week……

During the day, how many times do you pass urine on average?	1-6 times ☐ 7-8 times ☐ 9-10 times ☐ 11-12 times ☐ 13+ times ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you have to rush to the toilet to pass urine?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Does urine leak before you can get to the toilet?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
How often do you leak urine?	Never ☐ Once or less per week ☐ 2-3 times per week ☐ Once a day ☐ Several times a day ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Does urine leak when you are physically active, exert yourself, cough or sneeze?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you leak urine for no obvious reason and without feeling that you want to go?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
If you do change, what do you usually need to change?	Underclothes ☐ Panty liners/minipads ☐ Maxi/Super pads ☐ Nappies/Incontinence products ☐ Other-please specify	How many times a day do you change the ticked items because of leakage?	No change Once 2-3 times 4-5 times More than 5 times

Please describe any other urinary changes you have noticed……

……

Bowel Problem

Please think about how you have been in the last week:

Do you ever leak wind from your bowels without control?	Never □ Rarely □ Sometimes □ Usually □ Always □	How much of a problem is this to you?	Not a problem □ A bit of a problem □ Quite a problem □ A serious problem □
Do you ever leak liquid from your bowels without control?	Never □ Rarely □ Sometimes □ Usually □ Always □	How much of a problem is this to you?	Not a problem □ A bit of a problem □ Quite a problem □ A serious problem □
Do you ever leak solid from your bowels without control?	Never □ Rarely □ Sometimes □ Usually □ Always □	How much of a problem is this to you?	Not a problem □ A bit of a problem □ Quite a problem □ A serious problem □
Do you ever wear pads because of leakage from your bowels?	Never □ Rarely □ Sometimes □ Usually □ Always □	How much of a problem is this to you?	Not a problem □ A bit of a problem □ Quite a problem □ A serious problem □
Have bowel problems altered your lifestyle?	Never □ Rarely □ Sometimes □ Usually □ Always □	How much of a problem is this to you?	Not a problem □ A bit of a problem □ Quite a problem □ A serious problem □

Do you have to rush to the toilet to move your bowels? **Yes** ☐ **No** ☐

Can you wait at least 5 minutes? **Yes** ☐ **No** ☐

Problems with Intercourse

Have you tried sexual intercourse since your delivery? Yes ☐ No ☐

Did you experience any pain the last time you had intercourse? No ☐ Mild ☐ Moderate ☐ Severe ☐

Has the pain prevented you from having intercourse? Yes ☐ No ☐

Do you intend having a further pregnancy? Yes ☐ No ☐

Do you intend to try for a vaginal delivery in a future pregnancy? Yes ☐ No ☐

Would you request an Elective Caesarean Section next time? Yes ☐ No ☐

How Do You Feel?

Please underline the answer that comes closest to how you have felt in the last week.

I have been able to laugh and see the funny side of things:
As much as I always could
Not quite so much now
Definitely not so much now
Not at all

I have looked forward with enjoyment to things:
As much as I ever did
Rather less than I used to
Definitely less than I used to
Hardly at all

I have blamed myself unnecessarily when things went wrong:
Yes, most of the time
Yes, some of the time
Not very often
No, never

I have been worried or anxious for no good reason:
No, not at all
Hardly ever
Yes, sometimes
Yes, very often

I have felt scared or panicky for no good reason:
Yes, quite a lot
Yes, sometimes
No, not much
No, not at all

Things have been getting on top of me:
Yes, most of the time I haven't been able to cope at all
Yes, sometimes I haven't been able to cope as well as usual
No, most of the time I have coped quite well
No, I have been coping as well as ever

I have been so unhappy that I have had difficulty sleeping:
Yes, most of the time
Yes, sometimes
Not very often
No, not at all

I have felt sad or miserable:
Yes, most of the time
Yes, quite often
Not very often
No, never

I have been so unhappy I have been crying:
Yes, most of the time
Yes, quite often
Only occasionally
No, never

The thought of harming myself has occurred to me:
Yes, quite often
Sometimes
Hardly ever
Never

Pain Level

We would like you to indicate on the scale below how good or bad the pain from your perineum is today by drawing a cross at whichever point best indicates how you feel.

0-|-|-|-|-10-|-|-|-|-20-|-|-|-|-30-|-|-|-|-40-|-|-|-|-50-|-|-|-|-60-|-|-|-|-70-|-|-|-|-80-|-|-|-|-90-|-|-|-|-100

least imaginable pain

worst imaginable pain

What does your pain feel like? Not applicable, no pain ☐

Some of the words below describe your present pain. Circle ONLY those words that best describe it. Leave out any category that is not suitable. Use only a single word in each appropriate category- the one that best applies.

1	2	3	4
Flickering	Jumping	Pricking	Sharp
Quivering	Flashing	Boring	Cutting
Pulsing	Shooting	Drilling	Lacerating
Throbbing		Stabbing	
Beating		Lancinating	
Pounding			

5	6	7	8
Pinching	Tugging	Hot	Tingling
Pressing	Pulling	Burning	Itchy
Gnawing	Wrenching	Scalding	Smarting
Cramping		Searing	Stinging
Crushing			

9	10	11	12
Dull	Tender	Tiring	Sickening
Sore	Taut	Exhausting	Suffocating
Hurting	Rasping		
Aching	Splitting		

13	14	15	16
Fearful	Punishing	Wretched	Annoying
Frightful	Gruelling	Blinding	Troublesome
Terrifying	Cruel		Miserable
	Vicious		Intense
	Killing		Unbearable

17	18	19	20
Spreading	Tight	Cool	Nagging
Radiating	Numb	Cold	Nauseating
Penetrating	Drawing	Freezing	Agonising
Piercing	Squeezing		Dreadful
	Tearing		Torturing

How does your pain change with time? Not applicable, no pain ☐

Which word or words would you use to describe the pattern of your pain?

1	2	3
Continuous	Rhythmic	Brief
Steady	Periodic	Momentary
Constant	Intermittent	Transient

What kinds of things *relieve* your pain?……..

……

What kinds of things *increase* your pain?……..

……

How strong is your pain?

People agree that the following 5 words represent pain in increasing intensity. They are:

1	2	3	4	5
Mild	Discomforting	Distressing	Horrible	Excruciating

To answer each question below, write the number of the most appropriate word in the space beside the question.

Which word describes your pain right now? …….

Which word describes it at it's worst? …….

Which word describes it at it's least? …….

Which word describes the worst toothache you have ever had? …….

Which word describes the worst headache you have ever had? …….

Which word describes the worst stomach-ache you have ever had? …….

If given the choice would you take part in this study again? Yes ☐ No ☐ Don't know ☐

Thank you! Now please put the completed form in the envelope provided and return by post.

Appendix 18 Cover Letter 6 Week Questionnaire – Feasibility Study

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY

Dear _____,

I hope all is going well with you and your baby.

When you kindly agreed to take part in the Episiotomy in Instrumental Delivery Trial we indicated the follow-up questionnaire for the study could be posted to you or you could attend a clinic appointment here.

I know you will be very busy just now but, as we are interested to find out how you and your baby have been since delivery, would it be possible for you to complete the enclosed questionnaire and return it to me in the envelope provided. If you feel you would prefer to be seen by us please don't hesitate to contact me on 01382 660111, bleep number 4811.

We very much appreciate your help with the study and wish you well for the future.

Yours sincerely,

Maureen Macleod
Research Midwife

Appendix 19 REEDA Scoring System

Points	***Redness***	***Oedema***	***Ecchymosis***	***Discharge***	***Approximation***
0	**None**	**None**	**None**	**None**	**Closed**
1	**Within 0.25cm of incision bilaterally**	**Perineal, <1cm from incision**	**Within 0.25cm bilaterally or 0.5cm unilaterally**	**Serum**	**Skin separation 3mm or less**
2	**Within 0.5cm of incision bilaterally**	**Perineal +/- vulvar, between 1-2cm from incision**	**Between 0.25cm bilaterally or 0.5-2cm unilaterally**	**Sero-sanguinous**	**Skin and subcutaneous fat separation**
3	**Beyond 0.5cm of incision bilaterally**	**Perineal +/- vulvar, >2cm from incision**	**> 1cm bilaterally or 2cm unilaterally**	**Bloody, purulent**	**Skin, subcut fat and fascial layer separation**
SCORE					
				TOTAL	

Appendix 20 Case Note Sticker – Pilot Study

TAKING PART IN EPISIOTOMY TRIAL

TAKING PART IN EPISIOTOMY TRIAL

TAKING PART IN EPISIOTOMY TRIAL

TAKING PART IN EPISIOTOMY TRIAL

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TAKING PART IN EPISIOTOMY TRIAL

TAKING PART IN EPISIOTOMY TRIAL

Appendix 21 Obstetrician Thank You Letter – Pilot Study

Dept. of Maternal & Child Health Sciences
Ninewells Hospital & Medical School
Dundee DD1 9SY

Dear ……,

Delivery dates: 15.08.05

We were delighted to find that a woman, who had been recruited to participate in the Episiotomy in Instrumental Delivery trial, was randomised when the decision was made to deliver her by instrumental means. You were involved in this delivery, either directly or as a supervisor of junior staff and so we would like to thank you for your efforts.

As you will be aware a significant amount of time and energy is involved by both the study team and community midwives to recruit women in the antenatal period and it is very gratifying when the randomisation process is completed without a hitch.

May we take this opportunity to remind you that randomisation should be carried out on an intention to practice basis and so women being transferred to theatre for assessment prior to trial of forceps should be included.

If you would like to discuss the trial further, how to establish a woman's participation status or the randomisation process please do not hesitate to contact Maureen Macleod on bleep 4811.

Yours sincerely,

Deirdre Murphy
Professor of Obstetrics & Gynaecology

Maureen Macleod
Research Midwife

Appendix 22 Obstetrician Protocol Reminder Letter – Pilot Study

Dept. of Maternal & Child Health Sciences
Ninewells Hospital & Medical School
Dundee DD1 9SY

Dear ……,

Delivery date: 11.08.05

We were disappointed to find that a woman, who had been recruited to participate in the Episiotomy in Instrumental Delivery trial, was not randomised when the decision was made to deliver her by instrumental means.

You were involved in this delivery, either directly or as a supervisor of junior staff. As you know, we are very keen to include every recruited woman who has already consented and completed baseline questionnaires. A significant amount of effort is involved by both the study team and community midwives to recruit women in the antenatal period and if this is not to be wasted your vigilance is required to establish the participation status of ALL women whose instrumental delivery you attend.

Randomisation should be carried out on an intention to practice basis and so women being transferred to theatre for assessment prior to trial of forceps should be included.

If you would like to discuss the trial further, how to establish a woman's participation status or the randomisation process please do not hesitate to contact Maureen Macleod on bleep 4811.

Yours sincerely,

Deirdre Murphy
Professor of Obstetrics & Gynaecology

Maureen Macleod
Research Midwife

Appendix 23 Epistle Newsletter

EPISTLE

Issue 1, Nov 2004

RCT of Restrictive vs. Routine Use of Episiotomy in Instrumental Delivery

This study is now up and running and this newsletter is the first in a series to keep you up to date with its progress.

RECRUITMENT

The study was launched in mid September with a presentation to our Community midwives who are recruiting eligible women attending clinics at their GP surgery or when completing the birth plan with women at home.

To date 60 women have been recruited but mostly at high risk clinics in Ninewells.

WIN A BOTTLE OF WINE!
A bottle of wine is there to be won by the community midwife who recruits most women during November so come on girls lets see those consent forms come rolling in!

Have you seen this label?

TAKING PART IN EPISIOTOMY TRIAL

Well done to the midwives and obstetricians in Labour Suite who have spotted these labels on the front of recruits hand held notes and in the special recommendations for labour box. Recognising recruits and being ready to randomise them if they proceed to an instrumental delivery is crucial to the trial.

Results so far:

Recruited	60
Delivered	27
SVD	16
LUSCS	4
Instrumental	7
Randomised	5

Competition coming up!

Our trial sister centre in St Michaels Hospital, Bristol is starting to recruit from early December. Let's make sure they don't overshadow our efforts in Ninewells!

Any queries please contact Maureen Macleod: extn. 32979 or bleep 4811

Appendix 24 Delivery Room Door Notice

THIS WOMAN IS TAKING PART

IN THE EPISIOTOMY IN

INSTRUMENTAL DELIVERY TRIAL

Appendix 25 Data Extraction Proforma – Cohort Study

Cohort Study Data Sheet

Restrictive VS Routine Use of Episiotomy in Attempted Instrumental Delivery

Study No. ☐ **Site** ☐ **Patient Initials** ☐

MPI ☐ **Parity** ☐ + ☐ **Age** ☐

EDD ☐ **Postcode** ☐

Booking Weight (kg) ☐ **Height (cm)** ☐ **BMI** ☐

Medical Conditions

Smoking: No ☐ 1-10 ☐ 11-20 ☐ >20 ☐

Alcohol: Units per week: Pre pregnancy ☐ During Pregnancy ☐

Drug Abuse: None ☐ NonIVDU ☐ IVDU ☐

Complications of Current Pregnancy (please circle) None

PET	Polyhydramnios	Fetal Abnormality
IUGR	Oligohydramnios	Placenta Praevia
APH	Infection	Urinary incontinence y /n /dk

Other……

Labour: Spontaneous onset ☐ Induced ☐ Type of IOL ☐ Augmented ☐

Confirmed Gestation: ☐☐ + ☐

Pyrexia in labour(>38°): Yes ☐ No ☐

Liquor: Clear ☐ Meconium ☐ Purulent ☐ Malodourous ☐

Intrapartum Haemorrhage: No ☐ Yes ☐

<5ooml ☐

>500ml ☐

Abruption ☐

Placenta Praevia ☐

Intrapartum analgesia: Tens ☐ Inhalation ☐ Parenteral ☐ Epidural ☐

Oral ☐ Specify …….. Pudendal block ☐ Spinal ☐ GA ☐

CTG Abnormalities: (As defined by NICE guidelines)	1st Stage	2nd Stage
Bradycardia	☐	☐
Tachycardia	☐	☐
Decelerations- Variable	☐	☐
Decelerations- Late	☐	☐
Reduced Variability	☐	☐

Length of: 1st Stage (hours) ☐ 2ndStage (mins) ☐ Active pushing (mins) ☐

Mode of Delivery: Attempt	1	2	3
Ventouse (NR)	☐	☐	☐
Ventouse (R)	☐	☐	☐
Low Cavity Forceps	☐	☐	☐
Mid cavity (NR)	☐	☐	☐
Rotational Forceps	☐	☐	☐
Caesarean Section	☐	☐	☐
Instrument Used	☐	☐	☐
Manual Rotation	☐	☐	☐

Indication for OVD: List in order of priority

1. Delay ☐ 2. Fetal Distress ☐ 3.Malposition ☐ 4.Other……

Decision to delivery time (mins): ☐

Grade of Operator 1: SHO ☐ SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐

Grade of Supervisor: SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐ None ☐

Grade of Operator 2: SHO ☐ SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐

Grade of Supervisor: SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐ None ☐

Grade of Operator 3: SHO ☐ SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐

Grade of Supervisor: SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐ None ☐

Sutured by: SHO ☐ SpR 1-3 ☐ SpR 4-5 ☐ Consultant ☐

Position diagnosed at Outset: OA ☐ OT ☐ OP ☐

Position at Delivery: OA ☐ OT ☐ OP ☐

Station: 0 ☐ +1 ☐ +2 ☐ +3 ☐

Moulding: None ☐ Mild/Mod (+1/+2) ☐ Severe (+3) ☐

Caput: None ☐ Mild/Mod ☐ Severe ☐

No. Pulls ☐ **No. Contractions** ☐

Early Maternal Complications

EBL ☐ 1° PPH ☐ 2° PPH ☐ Transfusion ☐ No units transfused ☐

Perineal Trauma: None ☐ Vag Wall laceration ☐ Cervical Laceration ☐

Labial laceration ☐ 1° Tear ☐ 2° Tear ☐

3°a Tear ☐ 3°b Tear ☐ 3°c Tear ☐ 3° unspecified ☐ 4° Tear ☐

Episiotomy ☐ Extended Episiotomy ☐

Until Hospital Discharge:
Perineal Infection ☐ Haematoma ☐ Resutured / Drained ☐

Antibiotics ☐ **Reason for antibiotics** ……..

Analgesia: Inpatient Strong ☐ Moderate ☐ Mild ☐

Outpatient Strong ☐ Moderate ☐ Mild ☐

Bladder

Blood Stained Urine ☐ Catheter>24hrs ☐ How long? (Days) ☐

Neuropathic/Retention ☐ UTI ☐ Incontinence ☐

Altered sensation ☐

Bowel

Neuropathic sphincter ☐ Incontinence of flatus ☐ Incontinence of faeces ☐

Postnatal inpatient days ☐

Maternal readmission Y/N Describe…….

Baby Detail **Identification No** ☐ **Time of Del** ☐

Birthweight ☐ **Calculated BW centile** ☐ **Head Circumference** ☐

Sex: Male ☐ Female ☐

Apgars: 1 min ☐ 5 min ☐ 10 min ☐

Cord Gases:

Arterial	pH				.		
	BE				.		
Venous	pH				.		
	BE				.		

Resuscitation:

Nil (incl suction+O2) ☐ IPPV<10mins ☐ IPPV>10mins ☐ Cardiac massage ☐

Time to 1st Spontaneous Breath: ☐

Trauma: - Bruising: No ☐ Mild ☐ Mod ☐ Severe ☐

Laceration: No ☐ Mild ☐ Mod ☐ Severe ☐

Encephalopathy: No ☐ Mild ☐ Mod ☐ Severe ☐

Cephalhaematoma: - Yes ☐ No ☐

Retinal Haemorrhage: - Yes ☐ No ☐

Brachial Plexus Injury: - Yes ☐ No ☐

Shoulder Dystocia: - Yes ☐ No ☐

Fracture: - Yes ☐ No ☐

Other……

Admission to NICU: Yes ☐ No ☐

Duration of Stay: Days ☐ Weeks ☐

Baby Follow Up Yes ☐ No ☐

Discharge Status: Normal ☐ Abnormal ☐ Suspect ☐ Neonatal Death ☐

Baby readmission Y/N Describe……

Any other relevant information ……

……

……

……

……

……

Appendix 26 Participant Information Sheet – Pilot Study

UNIVERSITY OF DUNDEE

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY

Randomised controlled trial of restrictive versus routine use of episiotomy for instrumental vaginal delivery – a two-centre pilot study

Patient Information Sheet

You are being invited to take part in a research study. Before you decide to take part, it is important that you understand why the research is being done and what it will involve. Please take time to read this information carefully and discuss it with others. Please ask us if there is anything that is not clear or about which you would like more information.

Who is organising and funding the research?

The study is being organised jointly by the University of Dundee, Ninewells Hospital, Dundee and St. Michael's Hospital, Bristol. Funding is provided by Tenovus, Scotland.

What is the purpose of the study?

The purpose of the study is to look at two different approaches to the use of episiotomy- a cut to widen the vaginal opening- when women need a forceps or vacuum delivery. The two options that are being compared are **- restrictive use** (only if tearing becomes apparent) and **routine use** (in all cases).

Research already completed comparing restrictive use of episiotomy with routine use of episiotomy during spontaneous vaginal birth suggests that there are significant benefits in adopting a restrictive policy. There are some risks and benefits for both mother and baby associated with each approach and we are trying to find out which is the best option to use when doing a forceps/vacuum delivery.

Both methods are commonly used but their use varies from doctor to doctor. We want to give doctors/midwives more information about the various risks and benefits of each approach in order to help them better decide how to use episiotomy in forceps/vacuum deliveries. Women are also becoming more involved in their own health care and it is important that their decisions can be based on sound evidence.

Why have I been chosen?

We are carrying out this study in the maternity units in Ninewells hospital, Dundee and St. Michael's Hospital, Bristol. We are trying to contact every woman who is booked to deliver in these

hospitals by a normal vaginal delivery. 1 in 8 women who plan to deliver normally however need a forceps or vacuum delivery and if this decision is made with you, it is at that point you would be allocated to one or other type of episiotomy use. Over the next 18 months we hope to have around 200 women like you taking part in the study.

Do I have to take part?

It is entirely your choice whether you take part or not. If you do decide to take part you will be given this information sheet to take home and will be asked to sign a consent form, a copy of which you will also be given to keep. You will of course be free to change your mind at any time during the study, without having to give any reason and this will not affect the way we look after you. If you decide not to take part, your delivery will be managed in the usual way through discussion with your obstetrician and midwife.

The Medical Research Ethics Committee for Scotland, which has a responsibility for looking at all proposed research studies on humans, has examined this study (and a pilot form of it) and raised no objections to it. It is a requirement that your records in this research and any relevant medical records be made available for scrutiny by monitors from the funders, NHS Tayside and the regulatory authorities.

What will happen during the study?

Everyone that agrees to take part in the study will, if a decision is made to deliver them by forceps/vacuum, be allocated by chance to one of two ways of using episiotomy as part of their delivery. This is done by means of a computer program based in the labour suite and will be completed by a member of you care team. The two groups will then be compared at the end of the study to find out which way, if any, best helps women and babies to recover following delivery.

Depending on which group you are in you will be managed with:

1. A **Restrictive** approach when episiotomy is only used if tearing of the birth canal appears to be happening.

2. A **Routine** approach when episiotomy will be performed in all cases to avoid tearing.

In both groups you will be asked to complete a total of 4 questionnaires- one before your baby is born, one the day or two after birth and one six weeks after birth to let us know about your recovery and your baby's progress. You will also be invited back to hospital for a postnatal appointment 6 weeks after your baby is born to discuss your recovery from delivery. We plan, finally, to send you a follow-up questionnaire when your baby is 1 year old. You are free, at any time, to leave out any question you do not feel happy to answer.

Will my taking part in this study be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. A researcher on the study will need to look at your hospital records for information about your method of delivery. All information about you will have your name removed so that you cannot be recognised by it. We will store all information collected about you in locked cabinets or

on password protected computers (even if you at any time withdraw from the study) for a length of 15 years. We will also ask for your consent to inform your GP that you are taking part in the study.

What will happen to the results of the study?

The study will last for 18 months. If it is successful we hope to extend it to other hospitals in order to test this research question in the greatest number of cases possible. We hope the results will provide clear information for women and their obstetricians about their options at the time of forceps/vacuum delivery. A report will be produced at the end of the study and the main results will be published in medical journals. This can take up to a year after the end of the study but if you would like a copy of the results please let us know.

What will happen if I am unhappy with my treatment on the study?

If you wish to complain about any aspect of your treatment during the course of this study, this would initially be dealt with by the research team, but if a satisfactory resolution was not achieved you will of course have access to the normal Health Service complaints procedure. Participation in no way affects your statutory rights.

Taking part in this research may have an effect on any private medical / life cover you may have but please feel free to seek further advice on this.

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it.

Contact for further information regarding this study:

Maureen Macleod,
Maternal & Child Health Sciences 2,
Ninewells Hospital & Medical School.
Dundee DD1 9SY

Tel : 01382 632979 e mail: m.macleod@dundee.ac.uk

Thank you for your consideration of this study, as without you it would not be possible.

Appendix 27 Consent Form – Pilot Study

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY

Randomised controlled trial of restrictive versus routine use of episiotomy for instrumental vaginal delivery – a two-centre pilot study

CONSENT FORM

Please write your initials in each box

1. I have read and understood the information sheet dated 22nd June 04 (version 4) for the above study and have had the opportunity to ask questions.I have retained a copy of the information sheet. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I give permission for sections of my medical notes to be looked at by a researcher to obtain information relevant to the study. I understand that all information will remain strictly confidential. ☐
4. I agree that all information collected about me as part of the study can be stored and analysed by the research team at the University of Dundee ☐
5. I give permission for my GP to be informed about my participation in this study. ☐
6. I agree to take part in the above study. ☐
7. I have received a copy of the consent form dated 23rd February 05 (version 3) for the study. ☐

Name of participant	Signature	Date of birth	Date of signing

Name of researcher	Signature	Date of signing

Name of GP	Practice Name

1. A copy to the participant
2. A copy to the researcher
3. A copy to be retained in the hand held maternity notes

Consent form, Version 3, 23rd February 2006

Appendix 28 Randomisation Instruction Sheet – Pilot Study

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY

EPISIOTOMY TRIAL

This woman has consented to participate in the above trial.

If she is to be delivered instrumentally **RANDOMISE**

Double click on Episallocate icon on computer at LS desk

Insert password – maureenm

Enter woman's CHI number

Leave Stratum as 1

Press submit

Allocation will be to:

Routine Episiotomy- in all cases
or
Restrictive Episiotomy- only if tearing or clinically indicated

Appendix 29 1 Year Questionnaire – Pilot Study

Randomised controlled trial of restrictive versus routine use of episiotomy for instrumental vaginal delivery – a two-centre pilot study

VOLUNTEER QUESTIONNAIRE – 1 YEAR POSTNATAL

STUDY No. ☐

Thank you very much for taking the time to complete this questionnaire at such a busy time. We hope it won't be too difficult to fill out but if you have any comments regarding the questionnaire please add them below. Please feel free to leave out any question you do not feel comfortable answering. Your help is very much appreciated.

……
……
……

Your Child's Health

Has your child been referred to hospital clinic since he/she was born? Yes ☐ No

If yes, why? ……

Was he/she admitted to hospital? Yes ☐ No ☐

Did he/she have any treatment there? Yes ☐ No ☐

What?……

Has your child attended for all routine screenings? Yes ☐ No ☐

Has your Health Visitor/Doctor picked up any physical or developmental problems? If so please tell us about them briefly below……

……

……

Your Health

Are you attending your GP or a hospital clinic for any delivery related complications? Yes ☐ No ☐

If yes, why?…… ……

……

Have you been admitted to hospital because of them? **Yes** ☐ **No** ☐

Why?……

Did you have any treatment there? **Yes** ☐ **No** ☐

What?……

Have you received any antibiotics for any <u>delivery related infection</u>? Yes ☐ **No** ☐

Why?……

Urinary Symptoms

Do you ever have a problem with urine leaking? **Yes** ☐ **No** ☐

If you have urine leakage, how long ago did it begin? **Months** ☐ **Years** ☐ **(please insert a number)**

Did you have this problem prior to your pregnancy? **Yes** ☐ **No** ☐

Do you regularly perform pelvic floor exercises? **Yes** ☐ **No** ☐

Now think about the last week……

During the day, how many times do you pass urine on average?	1-6 times ☐ 7-8 times ☐ 9-10 times ☐ 11-12 times ☐ 13+ times ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you have to rush to the toilet to pass urine?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Does urine leak before you can get to the toilet?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

How often do you leak urine?	Never ☐ Once or less per week ☐ 2-3 times per week ☐ Once a day ☐ Several times a day ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

Does urine leak when you are physically active, exert yourself, cough or sneeze?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

Do you leak urine for no obvious reason and without feeling that you want to go?	Never ☐ Occasionally ☐ Sometimes ☐ Most of the time ☐ All of the time ☐	How much of a problem is this for you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

If you do change, what do you usually need to change?	Underclothes ☐ Panty liners/minipads ☐ Maxi/Super pads ☐ Nappies/Incontinence products ☐ Other-please specify ☐	How many times a day do you change the ticked items because of leakage?	No change Once 2-3 times 4-5 times More than 5 times

Please describe any other urinary changes you have noticed……

……

……

Problems with Intercourse

Have you been sexually active since your delivery? **Yes** ☐ **No** ☐

Did you experience any pain the last time you had intercourse? **No** ☐ **Mild** ☐ **Moderate** ☐ **Severe** ☐

Has the pain prevented you from having intercourse? **Yes** ☐ **No** ☐

Bowel Problems

Please think about how you have been in the last week:

Do you ever leak wind from your bowels without control?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you ever leak liquid from your bowels without control?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you ever leak solid from your bowels without control?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Do you ever wear pads because of leakage from your bowels?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐
Have bowel problems altered altered your lifestyle?	Never ☐ Rarely ☐ Sometimes ☐ Usually ☐ Always ☐	How much of a problem is this to you?	Not a problem ☐ A bit of a problem ☐ Quite a problem ☐ A serious problem ☐

Do you have to rush to the toilet to move your bowels? **Yes** **No** ☐

Can you wait at least 5 minutes? **Yes** **No** ☐

How Do You Feel?

Please underline the answer that comes closest to how you have felt in the last week.

I have been able to laugh and see the funny side of things:
As much as I always could
Not quite so much now
Definitely not so much now
Not at all

I have looked forward with enjoyment to things:
As much as I ever did
Rather less than I used to
Definitely less than I used to
Hardly at all

I have blamed myself unnecessarily when things went wrong:
Yes, most of the time
Yes, some of the time
Not very often
No, never

I have been worried or anxious for no good reason:
No, not at all
Hardly ever
Yes, sometimes
Yes, very often

I have felt scared or panicky for no good reason:
Yes, quite a lot
Yes, sometimes
No, not much
No, not at all

Things have been getting on top of me:
Yes, most of the time I haven't been able to cope at all
Yes, sometimes I haven't been able to cope as well as usual
No, most of the time I have coped quite well
No, I have been coping as well as ever

I have been so unhappy that I have had difficulty sleeping:
Yes, most of the time
Yes, sometimes
Not very often
No, not at all

I have felt sad or miserable:
Yes, most of the time
Yes, quite often
Not very often
No, never

I have been so unhappy I have been crying: **Yes, most of the time**
Yes, quite often
Only occasionally
No, never

The thought of harming myself has occurred to me: **Yes, quite often**
Sometimes
Hardly ever
Never

Pain Level

Do you still experience any delivery related pain? **Yes** ☐ **No** ☐

If yes please tell us about it briefly below……

……..

……..

Future Plans

Do you intend having a further pregnancy? **Yes** ☐ **No** ☐

Do you intend to try for a vaginal delivery in a future pregnancy? **Yes** ☐ **No** ☐

Would you request an Elective Caesarean Section next time? **Yes** ☐ **No** ☐

If given the choice would you take part in this study again? **Yes** ☐ **No** ☐ **Don't know** ☐

Thank you! Now please put the completed form in the envelope provided and return by post.

Appendix 30 Cover Letter 1 Year Questionnaire – Pilot Study

UNIVERSITY OF DUNDEE

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY

Dear Jillian,

Congratulations on your baby's first birthday. I hope you are both doing well.

I am writing with regard to the Episiotomy in Instrumental Delivery Trial you kindly took part in when you had your baby in Ninewells.

We said at that time we would like to follow your progress up about one year on and so I enclose a **last** questionnaire for the study.

I know this is a very busy time but if you could take just a few minutes to fill out the questionnaire - any information you give us is very helpful for us to understand what the best approach is to episiotomy for future mum's having an instrumental delivery.

Please return the completed questionnaire in the envelope provided.

Thank you for all your help with the study and we wish you and your child well in the future.

Yours sincerely,

Maureen Macleod
Study Co-ordinator

Appendix 31 Reminder Letter 1 Year Questionnaire – Pilot Study

Dept. of Maternal & Child Health Sciences,
Ninewells Hospital & Medical School,
Dundee DD1 9SY

Dear Samantha,

We recently sent you a follow-up questionnaire for the Episiotomy in Instrumental Delivery trial and have not as yet received it back completed.

I know this is a very busy time, but even if you feel you have no symptoms or pain to report, the information you give us is really important and will help us to give the highest standard of care to women needing help to deliver in the future.

I have enclosed a replacement questionnaire in case you have mislaid the original and would urge you to spend a few moments completing it.

Please return the questionnaire in the freepost envelope provided.

Our sincere thanks again for helping with this study.

Yours sincerely,

Maureen Macleod
Research Midwife

Appendix 32 Tables illustrating the data analysis plan – feasibility study

Maternal and neonatal characteristics in relation to randomised versus non randomised participants at OVD

	Randomised n=6	Non randomised n=24
Primiparae (%)	6(100.0)	16(66.7)
Maternal Age >35 years (%)	2(33.3)	7(29.2)
Body mass index >30 [i] (%)	0(0.0)	4(21.1)
Pre-eclampsia (%)	1(16.7)	0(0)
Suspected IUGR [ii] (%)	0(0)	0(0)
Induction of labour (%)	2(33.3)	10(41.7)
Small for gestational age (%) [iii]	0(0)	0(0)
Gender male (%)	5(83.3)	15(62.5)
Gestational age (wks + days) Mean (SD[iv](days)) [range]	40^{+4} (7) [39^{+1} – 41^{+5}]	40^{+6} (5) [39^{+3} – 41^{+6}]
Birth weight (g) Mean (SD) [range]	3377 (172) [3100 – 3600]	3665 (408) [3080 – 4560]
Head circumference (cm) Mean (SD) [range]	34.9 (0.7) [34.0 – 36.0]	35.7 (1.0) [34.0 – 37.0)]

i BMI measured as booking weight (kg)/height 2 (m).

ii Suspected intra uterine growth restriction (IUGR). – abdominal circumference <10th percentile on ultrasound scan

iii Small for gestational age baby based on calculated birth weight <10th percentile.

iv standard deviation (SD)

Labour and delivery factors in relation to randomised versus nonrandomised participants at OVD

	Randomised n=6	Non randomised n=24
Epidural analgesia (%)	4(66.7)	12(50.0)
Pudendal block (%)	1(16.7)	6(25.0)
Spinal anaesthesia (%)	1(16.7)	3(12.5)
Labour duration > 12 hours [i] (%)	3(50.0)	17(81.0)
Second stage duration >2 hours [ii] (%)	6(100.0)	14(58.3)
Pathological CTG [iii] (%)	1(16.7)	7(30.3)
Meconium stained liquor (%)	0(0)	5(20.8)
Fetal malposition [iv] (%)	2(33.3)	5(20.8)
Vacuum delivery (%)	2(33.3)	10(41.7)
Forceps delivery (non-rotational) (%)	2(33.3)	12(50.0)
Forceps delivery (rotational) (%)	2(33.3)	2(8.3)
Spontaneous vaginal delivery (%)	0(0)	0(0)
Caesarean section (%)	0(0)	0(0)
Operator SHO (%)	0(0)	1(4.3)
Operator SpR Year 1-3 (%)	2(33.3)	18(78.3)
Operator SpR Year 4-5+ (%)	2(33.3)	4(17.4)
Operator Consultant (%)	2(33.3)	0(0)
Number of pulls > 3 (%)	0(0)	1(4.3)
Use of sequential instruments (%)	0(0)	3(12.5)

i Total labour duration included first and second stage of labour.

ii Included the passive and active phases of second stage of labour.

iii Cardiotocograph (CTG) showing persistent late decelerations, tachycardia (>160 bpm) with decelerations, bradycardia (<100 bpm) for >10minutes in second stage.

iv Occipto-transverse and occipito-posterior positions of the fetal head.

Maternal and neonatal characteristics in relation to routine versus restrictive use of episiotomy at OVD

	Routine n=4	Restrictive n=2
Primiparae (%)	4(100.0)	2(100.0)
Maternal Age >35 years (%)	2(50.0)	0(0.0)
Body mass index >30 [i] (%)	0(0.0)	0(0.0)
Pre-eclampsia (%)	1(25.0)	0(0)
Suspected IUGR [ii] (%)	0(0)	0(0)
Induction of labour (%)	2(50.0)	0(0.0)
Small for gestational age (%) [iii]	0(0)	0(0)
Gender male (%)	4(100.0)	1(50.0)
Gestational age (wks + days) Mean (SD(days)) [range]	40^{+3} (7) [39^{+1} – 41^{+5}]	40^{+6} (6) [40^{+2} – 41^{+4}]
Birth weight (g) Mean (SD) [range]	3420(133) [3280 – 3600]	3290(269) [3100 – 3480)]
Head circumference (cm) Mean (SD) [range]	34.8(0.5) [34.0 – 35.0]	35.2(1.2) [34.3 – 36.0)]

i BMI measured as booking weight (kg)/height 2 (m).

ii Suspected intra uterine growth restriction (IUGR). – abdominal circumference <10th percentile on ultrasound scan

iii Small for gestational age baby based on calculated birth weight <10th percentile

Labour and delivery factors in relation to routine versus restrictive use of episiotomy at OVD

	Routine n=4	Restrictive n=2
Epidural analgesia (%)	3(75.0)	1(50.0)
Pudendal block (%)	1(25.0)	0(0)
Spinal anaesthesia (%)	0(0)	1(50.0)
Labour duration > 12 hours [i] (%)	1(25.0)	2(100.0)
Second stage duration >2 hours [ii] (%)	4(100.0)	2(100.0)
Pathological CTG [iii] (%)	0(0)	1(50.0)
Meconium stained liquor (%)	0(0)	0(0)
Fetal malposition [iv] (%)	0(0)	2(100.0)
Vacuum delivery (%)	2(50.0)	0(0)
Forceps delivery (non-rotational) (%)	2(50.0)	0(0)
Forceps delivery (rotational) (%)	0(0)	2(100.0)
Spontaneous vaginal delivery (%)	0(0)	0(0)
Caesarean section (%)	0(0)	0(0)
Operator SHO (%)	0(0)	0(0)
Operator SpR Year 1-3 (%)	1(25.0)	1(50.0)
Operator SpR Year 4-5+ (%)	2(50.0)	0(0)
Operator Consultant (%)	1(25.0)	1(50.0)
Number of pulls > 3 (%)	0(0)	0(0)
Use of sequential instruments (%)	0(0)	0(0)

i Total labour duration includes first and second stage of labour.

ii Includes the passive and active phases of second stage of labour.

iii Cardiotocograph (CTG) showing persistent late decelerations, tachycardia (>160 bpm) with decelerations, bradycardia (<100 bpm) for >10minutes in second stage.

iv Occipto-transverse and occipito-posterior positions of the fetal head.

Maternal outcomes in relation to routine versus restrictive use of episiotomy at OVD

	Routine n=4	Restrictive n=2
Third/Fourth degree tear (%)	0(0)	0(0)
Shoulder dystocia (%)	0(0)	0(0)
PPH>500mls (%)	1(25.0)	0(0)
Urinary catheter > 24 hours (%)	1(25.0)	1(50.0)
Urinary retention (%)	0(0)	0(0)
Urinary Incontinence (%)	1(25.0)	0(0)
Faecal incontinence (%)	1(25.0)	0(0)
Inpatient moderate/strong analgesia use (%)	4(100.0)	2(100.0)
Outpatient moderate/strong analgesia use i (%)	2(50.0)	1(50.0)
Postnatal admission > 3 days (%)	3(75.0)	1(50.0)
Perineal infection i (%)	0(0.0)	1(50.0)
Any antibiotic use i (%)	2(50.0)	1(50.0)

i Up to the 10th postnatal day

Neonatal outcomes in relation to routine versus restrictive use of episiotomy at OVD

	Routine n=4	Restrictive n=2
Neonatal resuscitation [i] (%)	0(0)	1(50.0)
Neonatal trauma [ii] (%)	1(25.0)	0(0)
Severe trauma [iii] (%)	1(25.0)	0(0)
pH umbilical artery < 7.10 (%)	0(0)	1(50.0)
Base excess artery < -12.0 (%)	0(0)	0(0)
Apgar score at 5 min < 7 (%)	0(0)	0(0)
Apgar score at 1 min ≤ 3 (%)	0(0)	1(50.0)
Admission to NICU (%)	0(0)	1(50.0)

i Excludes oropharyngeal suction and facial oxygen

ii Includes bruising, skin abrasions, facial nerve palsy, Erb's palsy, fractures, retinal haemorrhage, encephalopathy and cephalhaematoma

iii Neonatal trauma excluding bruising and skin abrasions

Urinary, anal and sexual morbidities up to six weeks after operative vaginal delivery by episiotomy use

	Antenatal		6 weeks postpartum	
	Routine n=4	Restrictive n=2	Routine n=4	Restrictive n=2
Urgency of micturition (%)	3(75.0)	2(100.0)	2(50.0)	1(50.0)
Urge incontinence (%)	3(75.0)	1(50.0)	2(50.0)	1(50.0)
Stress incontinence (%)	2(50.0)	1(50.0)	1(25.0)	0(0)
Reduced urinary sensation (%)	0(0)	0(0)	0(0)	0(0)
Incontinence of flatus (%)	1(25.0)	2(100.0)	3(75.0)	1(50.0)
Incontinence of liquids (%)	0(0)	0(0)	1(25.0)	0(0)
Incontinence of solids (%	0(0)	0(0)	0(0)	0(0)
Urgency of defecation (%) [1]	1(25.0)	0(0)	0(0)	0(0)
Moderate/Severe dyspareunia (%)	0(0)	0(0)	1(25.0)	0(0)
Dyspareunia preventing intercourse (%)	0(0)	0(0)	1(25.0)	0(0)

1 Inability to wait 5 minutes after urge to defecate

Perineal pain up to six weeks after operative vaginal delivery by episiotomy use

	1st/2nd day		6 weeks	
	Routine n=3	Restrictive	Routine n=3	Restrictive
REEDA[1] Mean, (SD) [range]	3.75, (0.96)	2.50, (3.54)		
Perineal pain present (%)	3(100.0)	2(100.0)	0(0)	1(50.0)
Perineal pain visual analogue scale (0 – 100) Mean, (SD) [range]	26,(24) [2 – 50)	45, (28) [25 – 65]	0.25,(0.50) [0 – 1]	1.0, (1.41) [0 – 2]
McGill pain questionnaire: pain rating index[2] Mean, (SD) [range]	16, (14) [0 – 27)	2, (1) [1 – 2]	0,(0) [0 – 0]	0.50, (0.71) [0 – 1]
McGill pain questionnaire: number words chosen[3] Mean, (SD) [range]	9, (8) [0 – 16)	1, (0) [1 – 1]	0,(0) [0 – 0]	0.50, (0.71) [0 – 1]
McGill pain questionnaire: present pain intensity[4] Mean, (SD) [range]	1, (1) [0 – 2]	2, (0) [2 – 2]	0,(0) [0 – 0]	0.50, (0.71) [0 – 1]

1 Scoring system to assess perineal redness, oedema, bruising, discharge and alignment following episiotomy or tearing

2 Mean of numerical values assigned to descriptors chosen by participant to specify pain experience (possible range 0 – 79)

3 Mean of number of descriptors chosen by participants to specify pain experience (possible range 0 – 20)

4 Based on a 1 – 5 intensity scale to specify pain experience

Psychological morbidity up to six weeks after operative vaginal delivery by episiotomy use

	Antenatal		1st/2nd day postpartum		6 weeks postpartum	
	Routine n=4	Restrictive n=2	Routine n=4	Restrictive n=2	Routine n=4	Restrictiv n=23
EPDS Mean (SD) [range]	4.75(4.99) [1 – 12]	3.0 (4.24) [0 – 6]	3.67 (4.73) [0 – 9]	4.0 (5.66) [0 – 8]	2.5 (3.0) [1 – 7]	0 (0) [0 – 0]
Possible depression (EPDS≥13) (%)	0(0)	0(0)	0(0)	0(0)	0(0)	0(0)